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Barbara Blochman 11/10/98  
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## **INTRODUCTION**

### **Nature of the Problem**

Breast cancer is the most common cancer among women in the United States and is second only to lung cancer as a cause of cancer death (American Cancer Society, 1996). A woman's risk of developing breast cancer in her lifetime is currently 1 in 9 (American Cancer Society, 1995). The incidence of breast cancer has increased approximately 1-2% per year since that time, with death rates staying relatively stable (Kelsey & Horn-Ross, 1993; Marshall, 1993; Miller et al., 1993). As the incidence of breast cancer has increased, concern among health care professionals and women in general has also heightened. Anecdotal information and polls indicate that healthy adult women judge breast cancer to be their most serious health problem, despite the fact that women are at much higher risk of heart disease (Miller et al., 1993). Although several risk factors for breast cancer have been identified (e.g., family history, age at menarche and age at menopause, nulliparity), the majority of women who develop breast cancer do not have a significant family history, nor are they at high risk based on other known antecedent factors (Lerman et al., 1991; Marshall, 1993). Additionally, definitive primary prevention interventions for high-risk women have not been identified (Harris et al., 1992; Threatt, 1992), although ongoing clinical trials are evaluating promising medical and dietary interventions (National Surgical Adjuvant Breast and Bowel Project--NSABP, 1992).

### **Background of Previous Work**

At present, secondary prevention of breast cancer through screening is the most reasonable strategy for reducing the impact of breast cancer on American women (Kelsey & Horn-Ross, 1993). Screening programs that include mammography, clinical breast examination (CBE) and breast self-examination (BSE) have been associated with early detection of breast cancer (Foster et al., 1978; Harris et al., 1993; Kelsey & Horn-Ross, 1993). Use of mammography alone has been associated with a 25 to 30% reduction in mortality due to detection of early-stage tumors and concomitant decreased metastasis and morbidity and increased survival (American Cancer Society, 1996; Harris et al., 1992; Kelsey & Horn-Ross, 1993; Shapiro et al., 1982; Tabar et al., 1993; Threatt, 1992). CBE has been credited with the detection of an additional 8% of tumors not detected by mammography alone (Threatt, 1992), and CBE and BSE are particularly appropriate screening strategies in populations that have minimal access to mammography (Morrison, 1993). The National Cancer Institute, along with several other health research-oriented organizations have reached consensus regarding guidelines for annual mammography and CBE (Jacobs Institute of Women's Health, 1990) for women 50 and older. The American Cancer Society (ACS) (1996) recommends that all women conduct monthly BSE.

### **Impact of Perceived Risk on Screening Behaviors**

Inaccurate perceptions of a woman's risk for breast cancer can interfere with appropriate breast cancer screening behaviors. Previous research indicates that individuals greatly underestimate their own personal vulnerability to negative events such as crime victimization, natural disasters, and disease and disability, relative to the risk of others' (Fisher, 1991; Perloff, 1983; Weinstein, 1983, 1984, 1988, 1989). Results from health surveys suggest that people tend

to significantly underestimate their own chances of contracting and dying from cancer (Knopf, 1976). Perceiving oneself as less likely than average to be vulnerable may benefit non-victims by reducing their feelings of anxiety, depression and helplessness, allowing them to carry out everyday activities without being constantly on guard (Langer, 1975). However, there are several reasons why such perceptions may be maladaptive. Failing to take precautionary measures, such as wearing a seat belt or adopting a low fat diet, may be a result of what Weinstein (Weinstein, 1980) terms an "optimism bias", that is, the tendency to be unrealistically optimistic about one's own vulnerability. Being optimistically biased might lull the person into a false sense of security, and to think that precautionary behaviors, such as risk factor screening and dietary change, are unnecessary.

In a study conducted to determine, in part, the relationship between perceived risk and BSE, Olson and Mitchell (1989) found that most of their participants (175 women 20-89 years old) rated their risk of developing breast cancer as fairly low. Older women in particular did not identify themselves to be at increased risk for breast cancer. Studies of perceived risk in breast cancer have shown a relationship between having a family history of breast cancer and a tendency to perceive breast cancer risk as very high (Gronert et al., 1993; Kash, 1993; Lerman, 1993; Vernon et al. 1993). A tendency to underestimate or overestimate personal risk has been shown to have an impact on the practice of breast cancer screening activities. The research literature, however, is inconclusive as to whether or not perceived risk has a curvilinear or negative relationship to breast cancer screening (Alagna et al., 1987; Calnan, 1984; Champion, 1991; Clemow et al., 1993; Kash et al., 1992; Massey, 1986; Polednak et al., 1991). Olson and Mitchell (1989) recommend that health professionals need to help women realistically assess their risks by individualizing discussions of breast cancer risks to each woman. They suggest that increasing the congruence between estimated and perceived risks could help women make the crucial link between risk recognition and the benefit of appropriate screening.

### **Impact of Psychological Distress on Screening Behaviors**

Women report high levels of worry, and anxiety about their risk of developing breast cancer. This psychological distress is frequently found to predict low screening rates (Dean et al., 1986; Dermatis et al., 1989; Halper et al., 1989; Kash et al., 1992; Lerman et al., 1991). Increased psychological distress has been studied most often in women at high risk for breast cancer (e.g., strong family history) and those who have had abnormal screening mammograms (Lerman et al., 1991; Lerman & Schwartz, 1993; Dean et al., 1986). Increased cancer anxiety in these women was associated with poor CBE and BSE adherence. Other researchers have also documented a negative relationship between psychological distress and adherence to screening guidelines (Alagna et al., 1987; Kash et al., 1991; Lerman et al., 1990; Lerman et al., 1991; Lerman et al., 1995; Lerman et al., 1991), particularly among older women (Lerman et al. 1993). Over 27% of the women in the Kash et al. study (1991) had a level of psychological distress that was consistent with a need for counseling. These data suggest that relieving psychological distress through counseling could potentially improve breast cancer screening behaviors.

### **Risk Appraisal**

We are now able to project a woman's risk for breast cancer based on environmental, endocrine, genetic and pathologic factors (Sclafani, 1991). Models or algorithms for determining a woman's risk of breast cancer have been developed based on extensive epidemiologic data and

have been used to more specifically identify appropriate women for primary prevention and secondary prevention strategies. Risk appraisal, using the Gail breast cancer risk appraisal model (Gail et al., 1989; Gail & Benichou, 1994) is based on biological risk factors associated with breast cancer, including a woman's age at menarche, age at first live birth, number of previous breast biopsies, and number of first degree relatives with breast cancer. The risk appraisal is based on data from the Breast Cancer Detection Demonstration Project (BCDDP) (Baker, 1982) and is modeled differently depending on the woman's current age with weights assigned based on case control data from the earlier BCDDP. It produces a probability of developing breast cancer in the woman's lifetime on a scale of 0-100%. This model is being utilized in the current Breast Cancer Prevention Trial for estimating a woman's risk for breast cancer and providing her with this risk appraisal feedback (NSABP, 1992). It has also been used to assign women to specific risk categories for appropriate intervention and follow-up (Bondy et al., 1992). This model may slightly under-predict risk in older women, particularly those who do not adhere to annual mammography guidelines (Bondy et al., 1994).

The Breast Cancer Risk Appraisal from Group Health Cooperative of Puget Sound (Taplin et al., 1990) is also based on BCDDP data, as well as Surveillance, Epidemiology, and End Results (SEER) data for the GHC population and epidemiologic data from Seidman and associates (1982) and others. The GHC model includes an assessment of a woman's age, her history of prior breast cancer, family history of breast cancer in first-degree relatives, and her number of minor risk factors, including family history in a second-degree relative, early menarche, late menopause, first birth after age 30 or nulliparity, and previous breast biopsy for benign disease. Based on this appraisal, a woman is assigned to one of three risk levels (see Table 1; note that age-eligible participants will automatically be classified to the lower risk level 3 or higher risk levels of 2 or 1) (Taplin et al., 1990), describing her short-term risk of developing breast cancer.

### **Risk Appraisal Counseling**

Based on risk appraisals such as the Gail or GHC model, women can be counseled about their individual risk of breast cancer over the short-term and in her lifetime. Indeed, increasing public awareness of these risk factors have created a demand for more informed counseling of women who may be at high risk (Gail et al., 1989). Psychosocial counseling interventions for women at risk for breast cancer, timelines for such interventions, and a means for targeting them appropriately based on women's perceived and estimated risk have not been studied adequately. Because breast cancer does not occur solely in women deemed at high risk, risk appraisal counseling is appropriate for all women, particularly to decrease psychological distress, enhance more realistic perceptions of risk, improve adherence to recommended screening guidelines, and promote early detection of breast cancer (Kash et al., 1992; Lerman et al., 1996). Much is known about providing risk feedback regarding other types of health risks (McLeroy, 1989; Rowan, 1994; Wiegman-Oene & Gutteling, 1995). Thus, the health promotion literature and cognitive theories offer important insights for guiding such counseling about breast cancer risk. We have learned: (1) reactions to risk factor feedback are not always positive, nor do they always reflect accurately the feedback given; (2) several baseline factors predict reactions to risk feedback; and (3) counseling programs must be implemented to assist people in making meaning of and coping with risk information (Kash et al., 1995; Lerman et al., 1996). The present study applies what we know about risk information and health promotion in general to the specific case of risk for breast

cancer and evaluate its impact on breast cancer screening behaviors. Such evaluation is limited in the risk communication literature (Rohrmann, 1992).

### **Purpose of Present Work**

This study is investigating the impact of risk appraisal feedback and randomization to an immediate versus delayed group psychosocial counseling intervention (within three or eight weeks, respectively) on the primary outcomes of perceived-versus-estimated risk, psychological distress, and breast cancer screening behaviors. The specific aims of this study are to:

1. Determine the psychological distress of participants who receive breast cancer risk appraisal and randomization to immediate or delayed group psychosocial counseling,
2. Assess participants' screening behaviors over two years from the time of initial enrollment, based on their level of estimated risk,
3. Evaluate the association between perceived and estimated risk of breast cancer at baseline,
4. Describe short-term psychological reactions to breast cancer risk appraisal feedback, and
5. Describe sense of coherence, coping style, other health-related behaviors, social support, and perceived quality of life as secondary effects of the risk appraisal and counseling process.

### **Methods of Approach**

Women between the ages of 50 and 85 who have never had breast cancer are being invited to participate in this study of learning about and coping with breast cancer risk. Women are eligible if they respond to these recruitment efforts, contact the Fred Hutchinson Cancer Research Center (FHCRC), and agree to participate. This project will recruit approximately 350 women who wish to learn more about their risk for breast cancer.

Recruitment is being accomplished through multiple approaches and tailored messages. Lerman and associates (1994) emphasized the need to tailor recruitment messages for breast cancer health promotion trials to women's education levels. Initial recruitment of potential participants has taken advantage of the large number of ongoing and completed epidemiologic studies conducted at FHCRC that identify women willing to participate in other research studies (many of whom have indicated an interest in learning more about their risk for breast cancer). Early recruitment efforts have also been complemented and supported by community-based efforts and have included informational booths at breast cancer awareness and other health events, letters to area primary care practitioners about the study, and brochure placements in patient waiting areas. Physician referral has, in previous research, been found to be a highly efficient source of participants (Agras et al., 1982). Newspaper "human-interest" articles and paid advertisements are also being implemented to provide multiple opportunities for women to hear about the study. The Strang High Risk Breast Clinic in New York maintains its patient panel of about 700 to 800 high-risk women through public service announcements and advertisements (Halper et al., 1989). Mass mailings, based on Department of Motor Vehicle and other lists may be used, if needed. Previous research on recruiting for clinical trials has indicated that one of the more effective recruitment methods for primary prevention studies is mass-mailings (Meinert,



1986). Recruitment letters, the informational brochure, and the Brochure Placement Log are included in the Appendix.

All potential participants receive a screening telephone call, regardless of the method of initial contact and recruitment. This screening contact serves several purposes. First, the trained interviewer explains the study and the risk appraisal and counseling process to potential participants. Second, baseline demographic and tracking information are collected. Finally, the interviewer makes arrangements to send each potential participant a baseline questionnaire booklet, schedules a time for the risk appraisal feedback session, and schedules a paired set of group sessions (one immediate and one delayed). Telephone screening scripts and the Question and Answer Sheet used by the telephone interviewers are included in the Appendix. Participants are randomized to either the immediate or delayed session after the screening call.

### **Recruitment of African-American and Asian-American Women**

Women from various racial and ethnic groups, as well as socioeconomic levels, have been identified as particular groups with limited access to breast cancer screening. However, the recruitment of minority groups to research projects presents special challenges. We are recruiting from these groups using a two-phase process. During phase 1, the pre-contact phase, efforts are currently being made to familiarize the community with the study through direct social networking and involvement of community leaders and residents (Erwin et al., 1992). Media, such as neighborhood newspapers and local radio programs, have been identified as vehicles for publicizing the study, and articles are being written. In addition, primary care clinics serving the specific population, such as those clinics focusing specifically on providing services to African-American women, are being identified. Personal contacts will be made with clinic directors or other intermediaries to ascertain optimum ways of publicizing the study and recommendations for recruitment strategies (such as through local church groups). During phase 2, women will be actively recruited to participate in the study. During this phase, feedback on perceptions about the study will be obtained both from the participants and selected community leaders. Ongoing relationships with these community leaders will be maintained.

## **BODY**

### **Experimental Methods Used**

#### **Intervention**

##### **Risk Appraisal**

The individual risk appraisal session is scheduled during the screening phone call. The actual risk appraisal uses a computer algorithm to determine individual risk based on the Gail and on the GHC breast cancer risk appraisal models. Data items used for both the Gail and GHC risk assessment models are contained in Questionnaire Booklet One (baseline questionnaires), which is not included in the Appendix, because it contains material of limited distribution.

The risk appraisal feedback session with the nurse counselor provides participants with accurate information about the goals and procedures of the risk appraisal. Note that the randomization treatment assignment is not seen by the nurse counselor during the risk appraisal feedback session. A checklist for the session is contained in the Appendix, as is the Facilitator's Manual. Full, informed consent is discussed at this visit, and the printed study consent form for the project is signed before the session proceeds any further (see Appendix). Women who decline to participate are offered an information brochure on breast cancer screening.

During this individual session, the baseline questionnaire booklet is briefly reviewed for completeness and open-ended questions are posed to allow participants to process anxiety and expectations. The risk appraisal information is included on a "Risk Appraisal Information Sheet" provided to the participant at the initial risk appraisal feedback session (see Appendix). After the participant is given the risk appraisal information, the nurse counselor discusses participant concerns and subsequent study procedures. The participants are given an opportunity to ask questions relative to the risk appraisal, its meaning in their lives, and possible coping strategies. Questionnaire Booklet Two (post-appraisal data collection; not included in Appendix because it contains material of limited distribution) is handed out at the end of the session. At this time, participants also receive information about how to contact the nurse counselor with additional questions or concerns.

##### **Psychosocial Counseling Intervention**

In order to assess the effects of psychosocial counseling on selected variables, women are randomized to an immediate psychosocial counseling intervention or to an approximately eight-week delayed condition, which serves as a delayed treatment control group. This type of design has been used extensively in randomized trials of psychotherapy, attaining a balance between evaluating the treatment and providing treatment to all individuals who indicate a need for it.

The intervention consists of four sessions conducted in blocked groups of 4 to 8 women and held every week (see group session checklists in the Appendix). The content of the counseling sessions focuses on education about risk and screening, stress management, problem-solving, and social support (see Facilitator's Manual, Session Posters, and Handouts in the Appendix). A comprehensive risk information booklet developed at Fred Hutchinson Cancer Research Center is handed out during the first group session, but is proprietary material and therefore not included in this report. Participants are encouraged to contact the nurse/counselor in between visits with any concerns or questions that they have. The group and the nurse

counselor serve as an initial source of support. After the four-session module is completed, the women are referred to existing sources of group support in the community and are encouraged to meet on their own informally as a peer-led group. In other studies we have used this model of peer-led support groups with success in that approximately 50% of the groups continue to meet after the formal meetings are over. A peer-led group manual has been used in other studies to help peer leaders conduct groups and has been used to develop informational handouts on peer-led groups for the present study.

A 10% random sample of risk appraisal sessions are being tape-recorded to provide data from which to assure the quality and consistency of the ongoing study activities, based on the theoretical foundations and study protocol. These tape-recorded sessions will be transcribed and available for review by the project scientists, who will conduct the quality assurance evaluations. These tape-recorded sessions will also be available for secondary qualitative analysis of participants' individual responses and discussions during the sessions.

### **Data Collection and Management**

Data are collected on participants at four time points: at baseline, immediately following the risk appraisal feedback, three months after the initial visit, and at a long-term follow-up assessment, approximately 18 months after the completion of the group sessions (approximately two-years after the baseline visit; refer to Figure 1). Table 2 contains a timeline for measuring study constructs.

Before the first study visit, each participant is mailed a booklet of baseline forms to be completed at home and brought in for the scheduled risk appraisal feedback session (see Questionnaire Booklet One; not included in Appendix because it contains material of limited distribution). This baseline assessment includes measures of risk appraisal variables, perceived risk, psychological distress, health-related behaviors, and other psychosocial constructs of interest. In addition to providing baseline assessments of all measures used during the study (Specific Aim #3), this information is used to estimate each participant's appraised risk for breast cancer. Strategies to enhance response rates to the mailed questionnaire booklets are described in more detail below.

During their risk appraisal session, participants receive information about their estimated risk of developing breast cancer based on the analysis of the baseline assessment. At the end of this visit, all participants are given mailed a post-appraisal assessment booklet (not included in Appendix because it contains material of limited distribution) and asked to mail them back within one week. This information is used to describe short-term psychological reactions to breast cancer risk appraisal (Specific Aim #4).

Women randomized to the immediate psychosocial counseling condition, who have not returned their booklets within one week, are called and encouraged to bring their questionnaires to the first counseling session. Women in the delayed counseling group receive a follow-up reminder postcard to prompt them to return their forms within one week post-mailing.

Approximately three months after baseline, participants are mailed Questionnaire Booklet Three (post-group session time point for the immediate group and pre-group session time point for the delayed group; not included in Appendix because it contains material of limited distribution). At this point, only women in the treatment group will have participated in the counseling sessions, but all participants are told during the individual risk appraisal session to

expect the three-month follow-up booklets, complete them promptly, and return them in the accompanying postage-paid return envelope. This assessment provides information about the immediate versus delayed treatment condition (Specific Aims # 1 and 5).

Approximately 18 months after the group sessions (approximately two years after enrollment), all women will be mailed a fourth long-term follow-up booklet (not included in Appendix because it contains material of limited distribution). At this point, all participants will have completed the group psychosocial counseling sessions, and the long-term effects of differential risk feedback (i.e., higher risk categories versus low-risk category) will be assessed (Specific Aim #2).

### Measures

Measures of estimated and perceived risk of developing breast cancer, psychological distress, breast cancer screening behaviors, sense of coherence, coping style, other health-related behaviors, social support, and perceived quality of life are being used in this study. All measures are self-administered questionnaires. The Appendix does not include the questionnaire booklets containing these measures, because they contain material of limited distribution.

Estimated risk for breast cancer. Two measures are used to appraise each participant's estimated risk of developing breast cancer during her lifetime. The GHC Cancer Risk Appraisal assesses information about breast cancer risk factors (as well as additional items on medical and screening history, and selected lifestyle behaviors; see "Cancer Risk Appraisal" questionnaire in questionnaire booklets) (Taplin et al., 1989; Taplin et al., 1990). Based on risk factors identified in the GHC-Cancer Risk Appraisal, age-eligible women are assigned to one of three GHC levels of short-term risk for developing breast cancer (levels 3 through 1, with 1 being the highest risk; women 50 and older are automatically placed in GHC level 3 or in the higher risk levels 2 or 1). For most analyses, the moderate- and high-risk participants will be grouped together into a category of "higher risk", representing an estimated 17% of study participants. Although these estimates are based on the GHC population, significant differences in risk proportions for the current study are not anticipated.

Risk for breast cancer is also assessed using the Gail model for risk appraisal (see "Breast Cancer Risk Assessment" in the questionnaire booklets; Gail et al., 1989). This algorithm results in a probability of developing breast cancer in the woman's lifetime on a scale of 0-100% and has been described in the Background section.

Perceived risk. Perceived risk, which has been associated in previous studies with breast cancer screening (Taplin et al., 1989, 1990), is based on subscales of the Health Belief Model (HBM) questionnaire adapted by Champion (Champion, 1993) using the context of breast cancer and breast cancer screening behaviors (see the "Health and Cancer Beliefs" questionnaire in the questionnaire booklets). This instrument consists of six subscales: susceptibility (perceived personal risk of contracting breast cancer), seriousness of breast cancer, benefits of breast screening, barriers to screening, general health motivation, and confidence in ability to engage in screening behaviors. Items for all subscales are formatted with a 5-point scale from "strongly agree" to "strongly disagree". Using a random sample (N=581) of women 35 years and over, Cronbach's alpha reliability coefficients for the revised scales ranged from .80 to .93, and test-retest correlations ranged from .45 to .70 (Champion, 1993).

Perceived comparative risk, seriousness, and preventability are also assessed using items developed by Weinstein (see "Breast Cancer Risk Judgments" in the questionnaire booklets;

Weinstein, 1987). These items measure a participant's perceived risk compared to others her own age on a 7-point scale from "much below average" to "much above average", the perceived seriousness of the problem on a 5-point scale from "not at all serious" to "extremely serious or fatal", and the perceived preventability of the problem on 5-point scale from "can to nothing to reduce risk" to "completely preventable". Also included is the GHC Cancer Risk Appraisal measure of perceived risk (see "Cancer Risk Appraisal" in the questionnaire booklets), in which participants rate their chances of ever getting breast cancer in their lifetime on a continuous scale of 0-100% (corresponding to the Gail model estimated risk). Taplin's assessment also asks women to place themselves into one of four risk categories (no, low, medium, high) based on their perceived risk of breast cancer (corresponding to the GHC model estimated risk).

Psychological distress. Psychological distress, including anxiety, breast cancer worry, and depression has been associated with risk-appraisal feedback and subsequent health behaviors.

Anxiety is measured using the State-Trait Anxiety Inventory-Y Form (STAI). The STAI measures individual differences in the tendency to react with anxiety (see "General Thoughts and Feelings" questionnaire in the questionnaire booklets; Spielberger, 1983). It consists of 20 statements to which the respondent indicates the extent to which the statement is generally true for her on a 4 point scale from "almost never" to "almost always". Internal consistency of the scale in high school and college age-groups were all .90 or above (Spielberger, 1983). Test-retest reliability over 60 days ranged from .65 to .68. Validity of this instrument has been well-established by the authors.

Breast cancer worries are measured by a single 4-point item used to assess the presence of breast cancer worries that interfere with daily functioning (see "Breast Cancer Risk Judgments" questionnaire in the questionnaire booklets). This item has been shown to distinguish between persons at high and normal risk for breast cancer, and to relate to screening behaviors (Lerman et al., 1991).

Depression is measured by the Center for Epidemiological Studies-Depression Scale (CES-D), which measures the recent occurrence of symptoms of depression (see "Feelings and Behavior" questionnaire in the questionnaire booklets). For each of the 20 symptoms listed, the respondent indicates the frequency with which that symptom has occurred during the past week, from "rarely or none of the time (less than 1 day)" to "most or all of the time (5-7 days)". The item pool is not dominated by somatic complaints or symptoms and has been well-accepted in non-clinic samples. Internal consistency in 3 samples from the general population ranged between .84 to .85 (Radloff, 1977). Test-retest reliability at 3 months was moderate ( $r=.48$ ), as expected, since the CES-D was designed to measure the current level of depression. Validity of this instrument has been well-established.

Breast cancer screening behaviors. Breast cancer-related screening behaviors are assessed using specific items from the Cancer Risk Appraisal questionnaire (Taplin et al., 1989), which measures, in part, utilization of breast self-examination, clinical breast examination, and mammography screening. This instrument measures reported screening behavior over the previous year. Adherence to breast cancer screening guidelines are based on current ACS recommendations described in the Background section.

Sense of coherence. Sense of coherence, as a means for understanding cognitive appraisals and meaning-making during the process of risk appraisal and psychological counseling, is measured by the Coherence Scale developed by Lewis (1990), which measures a person's sense that her world is predictable and understandable (see "Coherence" questionnaire in the

questionnaire booklets). Development of this scale was based on Antonovsky's (1980) notion that people who experience their world as coherent see life as predictable, lawful, reasonable, and comprehensible (1990). The Coherence Scale includes 29 statements about the degree to which life is understandable and controllable rated on a 7-point scale from "not at all" to "to a large extent". The four subscales include certainty, trust, cognitive control, and personal effectiveness. Standardized Cronbach's alpha for the total scale was .93 for women with breast cancer (n=111) (Lewis, 1990). Internal consistency for the subscales ranged from .66 to .89. A correlation of .57 between the Coherence Scale total score and the Rosenberg Self-Esteem Scale score has been reported (Young Graham & Cowan, 1990).

Coping. Coping style has been associated with psychological distress and health-promotion behaviors (Horowitz et al., 1980; Lerman et al., 1990; Miller & Mangan, 1983). Coping style is measured using the Revised Ways of Coping Checklist (WCCL) (see "Coping" questionnaire in questionnaire booklets; Vitaliano, 1990). The WCCL is a shortened version of the Ways of Coping Checklist (Lazarus & Folkman, 1984) and includes 57 items with subscales of problem-focused coping, wishful thinking, seeking social support, avoidance, self-blame, other-blame, counting one's blessings, and religiosity. Internal consistencies of the subscales in samples of medical students and spouses of Alzheimers patients ranged from .72 to .90 (Vitaliano, 1990; Vitaliano et al., 1985).

Other health-related behaviors. Health-related behaviors are assessed using items taken from the Center for Disease Control's Behavioral Risk Factor Surveillance System (BRFSS) and the Cancer Prevention Research Program's Behavioral Risk Factor Survey (CPRP-BRFS; see "Health Behavior" questionnaire in the questionnaire booklet). The BRFSS is an ongoing surveillance system maintained by state health departments through random-digit dialed telephone interviews of adults over 18 years of age. The CPRP-BRFS is a similar survey that was conducted in Washington State by an NIH-funded program at FHCRC. Health-related behaviors include diet, alcohol intake, smoking habits, and cancer screening behavior.

Social support. Social support is a background variable known from previous research to be related to psychological distress, cognitive adaptation, perceived quality of life, and health responses (Cohen & Syme, 1985; Lindsey, 1988; Sarason et al., 1990). Social support is measured by the Personal Resources Questionnaire (PRQ) Part 2, as developed by Weinert and Brandt (see the "Personal Resources" questionnaire in the questionnaire booklets; Weinert & Brandt, 1987). This 25-item questionnaire, rated on a 7-point scale from "strongly disagree" to "strongly agree," measures five dimensions of perceived social support: intimacy, social integration, nurturance, worth, and assistance. Weinert & Brandt (1987) report an internal consistency (Cronbach's alpha) for the total scale of .91, with coefficients ranging from .79 to .88 for the five subscales. Test-retest reliability over a 4- to 6-week period in a sample of college graduates 30-37 years of age was .72. Validity testing in this sample showed the total scale score to be negatively correlated with standardized measures of anxiety, depression, neuroticism, and extroversion ( $r = -.28$  to  $-.42$ ,  $p < .001$ ).

Perceived quality of life. Perceived quality of life, as an important outcome of health status change, is assessed to evaluate the impact of risk appraisal on lifestyle over time. Perceived quality of life is used in this study, rather than more traditional quality of life measures that include such "illness-sensitive" dimensions as functional status or symptom distress. we expect that perceived quality of life will prove a more sensitive indicator of changes in lifestyle due to risk appraisal, rather than illness. Four indicators of perceived quality of life are obtained, including

the Quality of Life Index (Cancer II; see "Quality of Life-Satisfaction" and "Quality of Life-Importance" questionnaires in the questionnaire booklets), Current Quality of Life and Satisfaction with Current Quality of Life Scales (see "Quality of Life" questionnaire in the questionnaire booklets), and Global Well-Being Scale (see "Well-Being" questionnaire in the questionnaire booklets). The Quality of Life Index (Cancer II) (Ferrans & Powers, 1984) measures perceived quality of life in healthy as well as unhealthy individuals. The scale consists of two domains--satisfaction and importance--that allow a final weighted score of satisfaction based on how important the item is to the respondent. The 34-item Cancer II version has subscales of satisfaction with health and functioning, socioeconomic, psychological/spiritual, and family aspects of daily life. Each of the items is rated on a 6-point scale ranging from "very dissatisfied/unimportant" to "very satisfied/important". Standardized Cronbach's alpha has been reported at .90 for dialysis patients (Ferrans & Powers, 1984). Standardized Cronbach's alphas obtained for the subscales were .92, .88, .85, and .83 respectively, and .95 for the total scale (Young Graham & Cowan, 1990).

The Current Quality of Life Scale is a 1-item, 10-point scale rated from "poor" to "excellent" based on the respondent's perceived quality of life (Young & Longman, 1985). The Satisfaction with Current Quality of Life Scale is a 1-item, 10-point scale rated from "not at all satisfied" to "very satisfied" (Young & Longman, 1985). Following each scale item, respondents are asked to disclose what factors they were considering when they made their rating. Both items were chosen from a larger group of items as being the stronger estimates of perceived quality of life in subjects with malignant melanoma (Young & Longman, 1985; Young Graham & Longman, 1987). The Satisfaction with Current Quality of Life Scale has been correlated with the Quality of Life Index ( $r=.62$ ), the Graham Global Well-Being Scale ( $r=.56$ ), and the Current Quality of Life Scale ( $r=.76$ ) (Young Graham & Cowan, 1990).

Demographics. Demographic data collected on age, marital status, ethnicity, education, family income, and occupational position will be used to describe the study sample, evaluate the comparability of the control and intervention groups, and serve as covariates, as needed, in the analyses. Socioeconomic status will be calculated as an index based on education, occupational position, and income (Green, 1985).

#### Data Management

The Evaluation Shared Resource (ESR) of the FHCRC Cancer Prevention Research Program is overseeing and providing staff for screening contacts, participant tracking, assessment booklet and reminder postcard mailings, and post-mailing telephone data collection. The ESR is a shared resource managed by professional staff experienced in survey research methodologies. This unit has extensive experience in conducting large-scale mail, telephone, and in-person surveys. ESR staff oversee quality assurance, fielding operations, and recruitment and tracking procedures (see Appendix). Data are collected on self-report forms, coded and edited according to predetermined criteria, and key-entered into files prepared using a statistical software computer program. All data are kept strictly confidential with participant identification information available only to study staff. No individual identifying information will be reported.

### Strategies to Enhance Response Rates

To enhance the likelihood of a high response to the mailed questionnaires, strategies recommended by Dillman's Total Design Method for telephone and mail surveys are used (Dillman, 1978). Questionnaires are printed on a high-quality paper, in booklet form, with no data items on the front or back pages, and with an attractive cover design. Mailed materials are personalized (with the exception of the questionnaires and return envelopes) by including the participant's name on cover letters, postcards, and envelopes.

Initial mailings include the booklet of questionnaires, a postage-paid return envelope (as appropriate), and a cover letter explaining the study and emphasizing the importance of each participant's responses. Approximately one week after the initial mailing, a reminder postcard is mailed to all respondents to serve as a reminder to those who have not returned their questionnaire booklets. Approximately three weeks after the original mailing, a reminder phone call is made to and another booklet of questionnaires, return envelope, and cover letter are sent, if needed. If participants do not respond following postcard or telephone reminders, telephone attempts to collect critical data relating to the primary outcome (i.e., breast cancer screening behaviors) will be made after the last mail prompt. Intensive efforts will be made to collect data from those women who do not return their mailed follow-up assessments at approximately 18 months after group session completion (approximately two years after enrollment).

### Participant Tracking

Every attempt is being made to keep track of the women during the active intervention and follow-up. During the initial baseline sessions, women are asked to provide their own telephone number and address and the names and telephone numbers of two persons who are always likely to know their whereabouts. Participants are also provided with a "change of address" postcard that they are encouraged to complete and mail in if they move within the next two years. If a participant's telephone number has been disconnected or that she has moved, attempts will be made to locate her at her new residence. These efforts may include contacting directory assistance for the new telephone number and/or trying to reach the personal contacts indicated by each woman during her initial study visits. If a booklet of questionnaires is found to be undeliverable, similar procedures will be used to try to determine the participant's current address.

### Statistical Issues and Data Analysis

#### Evaluation and Data Analysis

Hypothesis 1: The group psychosocial counseling intervention will reduce psychological distress. At the 3 month assessment, we anticipate that the women who have had immediate counseling should have reduced psychological distress. Psychological distress at the 3-month assessment minus the post risk appraisal assessment will be calculated for the immediate-counseling and delayed-counseling groups. A two-sample t-test will be used to test the equality of means in the two groups. We expect that the difference in scores will be significantly lower in the group that has received the counseling.

Reduction in distress should also be related to a woman's perception of her risk of breast cancer. Psychological distress at the 3-month assessment minus distress following risk appraisal will be regressed on perceived risk at the 3-month assessment for women who have had the



immediate counseling intervention. We anticipate that the coefficient for perceived risk will be positive, indicating that women who perceive themselves at greatest risk will benefit most from the counseling. For this regression, perceived risk will be measured using the GHC questions or with Champion's perceived risk scale.

With the GHC representation of risk, the effect of perceived risk will be investigated through a two-way analysis of variance. The two factors are treatment group (two categories) and perceived risk (three categories, given that women in this age-group will automatically be classified into a level 3 or a higher level of 2 or 1). The outcome variable is psychological distress at 3 months minus psychological distress at risk appraisal. We anticipate that there will be a significant interaction between treatment and perceived risk. We anticipate no change in psychological distress in the delayed-counseling group across the three risk categories but greater change for the high risk groups. Analysis of variance will be used for comparing change in distress in the three perceived risk groups among women who have already received the counseling. Multiple comparisons will be used to further describe differences across the three risk groups.

Because psychological distress will also be measured at the long-term follow-up data collection point (approximately 18 months post-group sessions, or 2 years post-enrollment), we will be able to investigate the longer term effects of counseling. We will calculate changes in psychological distress between the long-term follow-up assessment and post-risk appraisal. All women will have received counseling by the long-term follow-up, so we cannot evaluate the effect of counseling versus no counseling in this situation. We will test whether the mean change is zero. If the counseling is effective then we should detect significant differences between the long-term follow up and post-risk appraisal measures. Maintenance in the women who received immediate counseling can also be investigated by comparisons with the 3-month assessment. We anticipate that a woman's perceived risk will have an impact on her level of psychological distress at all time points. Therefore, we will also incorporate effects of perceived risk into our modeling process, as we described above for the 3-month versus post-risk appraisal comparisons.

Hypothesis 2: Women who receive an appraisal that they are at a higher risk for breast cancer will comply better with screening recommendations than will women given low risk feedback. Because screening behavior recommendations for mammography, CBE and BSE differ slightly depending on the age group and risk status of women, whether or not a woman has adhered to the ACS recommendations for screening appropriate to her age and risk status will be evaluated. For each of the three screening behaviors, the association between risk group and compliance with screening recommendations will be assessed using categorical data analysis for the GHC representation. We anticipate that there will be increased compliance with higher risk of breast cancer. This will be assessed through use of tests for trend for the three screening modalities. Additionally, two-group comparisons (screening compliers / non-compliers) will be made, using the two-sample t-test.

We anticipate that conforming to screening recommendations will be greater following counseling. Logistic regression will be used to investigate the relation between following screening recommendations (yes/no) with time (baseline/long-term assessment) and perceived risk. We anticipate that the odds of screening will be increased at the long-term assessment and with greater perceived risk.

The analyses described above have focused on primary outcome variables. Other covariates such as age and education may have an effect on psychological distress and compliance

with screening recommendations. We will incorporate these variables into our models as well to assess this possibility.

Hypothesis 3: Participants will have misperceptions of their personal breast cancer risk at baseline. Because the two measures of estimated risk, one derived from the Gail model and one derived from the GHC model, are be used to investigate the relation between perceived and estimated risk for these two measures. The estimated probability of getting breast cancer, as determined from the Gail model will be regressed on a woman's perceived probability of getting breast cancer. If women have accurate perceptions of their risk at baseline, the slope of the line should be 1. Because we anticipate that women who are at low risk tend to underestimate their risk of getting cancer and those at high risk tend to overestimate their risk, the slope should be greater than 1. Therefore, a test of the hypothesis that the slope is 1 will be performed to confirm that women have misperceptions about their own risk prior to risk appraisal feedback. For the GHC model, estimated and perceived risk will first be dichotomized. Women who fall in the higher risk (GHC level 1) and the low risk categories of estimated or perceived risk (GHC level 3; women over 50 are automatically classified as a level 3 or above) will be grouped together and women who fall in the non-extreme category (GHC level 2) will be grouped together and a 2 x 2 table constructed. If women at lower risk tend to underestimate their risk and women at higher risk tend to overestimate their risk, then the number of women with non-extreme risk who perceive their risk as extreme will be large in comparison with the number of women with extreme risk who perceive their risk as non-extreme. (These are the off-diagonal frequencies in the 2 x 2 table.) McNemar's test will be used to assess the association between perceived and estimated risk. We will also investigate the relation between Champion's perceived risk scale and our two measures of perceived and estimated risk. Because Champion's scale is continuous, we will use regression and correlation for describing the relation between her scale and risk from the Gail model; one way analysis of variance will be used for associations with the GHC model.

Hypothesis 4: High risk appraisal will increase psychological distress. Psychological distress post risk appraisal will be modeled as a function of psychological distress at baseline and the difference between baseline perceived risk and estimated risk using multiple regression. This will enable us to investigate the effect of the disparity between perceived and estimated risk on the impact of the distress. We anticipate that the coefficient for baseline distress will be positive, the coefficient for estimated risk will be positive and the coefficient for perceived minus estimated risk will be negative. We will consider various ways of measuring perceived and estimated risk for this analysis. Estimated risk will be determined from the Gail and GHC models and perceived risk will be determined from these two models and Champion's perceived breast cancer risk scale. When risk is categorized for the GHC representation, we will create 3 indicator variables for estimated risk for inclusion in the regression model.

Hypothesis 5: Participants' sense of coherence, coping style, other health-related behaviors, social support, and perceived quality of life will change over time depending on level of estimated risk. While our primary outcome measure is psychological distress, we will be taking measurements on a number of other variables, such as coherence, coping style, other health-related behaviors, social support, and perceived quality of life. We will perform the same analyses that we described above for Hypothesis 1 for these other variables. By comparing these measures at the 3-month assessment with the post-risk appraisal, we will be able to determine whether counseling has any short term effects on these measures. By making comparisons between the 3-month and long-term assessments we will be able to investigate whether women made any

changes in their coherence, coping style, social support, etc. as a result of the counseling and whether these were changes that were an immediate result of counseling or whether they took a while to establish. Also, the long-term follow-up assessment will enable us to investigate the maintenance of any changes that we made as a result of the counseling. For each of these variables, we will be able to assess the effectiveness of the treatment and its relation to perceived risk, estimated risk and on the discrepancy between perceived and estimated risk. These secondary outcomes will provide an opportunity to elaborate more fully women's reactions to risk appraisal and possible mediators of clinical outcomes. Such information can guide future interventions that specifically target groups of women in need of counseling and that focus interventions on their particular needs.

We anticipate that some women will drop out of the study. It is possible that women who learn that they are at lower risk of breast cancer may be more likely to drop out of the study. We will compare characteristics of women who do and do not drop out of the study.

### **Results Obtained based on Statement of Work**

#### **Hiring of personnel, purchase of equipment and supplies, development and testing of materials and intervention.**

Equipment and supplies have been purchased and personnel (nurse counselor, interviewer, data coding, entry, and management staff) have been hired and trained on study procedures to date.

The primary nurse counselor, Gretchen Zunkel, PhD, ARNP is a trained psychiatric nurse practitioner with extensive group counseling experience and a particular interest in breast cancer prevention. She is completing her doctoral work in December 1996 and will be continuing with this project while she is a post-doctoral scholar on the Women's Health Nursing Research Training Grant (Nancy Woods, PI) at the University of Washington Center for Women's Health Research. She will be assuming a faculty position at Arizona State University in January 1998.

Two other nurse counselors, Joelle Machia, RN and Stephanie Mehl, RN, MS were hired in April 1997 to help with individual and group intervention sessions.

Beti Thompson, PhD, a sociologist with comprehensive experience in health behavior change, cancer prevention, and intervention research, has been providing contributed mentor and co-investigator support to the Principal Investigator to provide ongoing support as Dr. Bowen's available time to support this effort has decreased. Ziding Feng, PhD, a biostatistician, and his biostatistical resource staff in the FHCRC Cancer Prevention Research Program has been providing statistical expertise on randomization schemes, data cleaning, and analysis.

Recruitment and informational materials about the study have been finalized and implemented (see Appendix). Supplementary health information materials have been finalized and implemented (focus group work was conducted to determine those materials most relevant and acceptable to potential participants). Preliminary development and focus group efforts indicate that many women obtain their information and questions about health issues, and particularly about breast cancer, from mass media, that they prefer accurate, but simple (e.g., non-clinical) health messages, and that these women have a broad range of women's health concerns (which come up as they consider and discuss breast health and breast cancer risk).

Intervention materials for both the nurse counselor and participant have been completed and implemented. The intervention content and materials were developed to be relevant,

accurate, and of high quality. These materials were evaluated, and revised based on appropriate literature, expert consultation, focus group input (separate from that used to determine acceptable health information), and initial implementation with study participants. Group session materials (handouts, posters) for the intervention sessions have also been finalized and implemented (see Appendix). Additional appropriate audiovisual materials for the group sessions (e.g., breast models, breast self-examination video) have also been obtained and implemented.

**Recruitment and screening of participants; Baseline Assessment packets mailed out and returned.**

We made a decision in year 1 to recruit women only between the ages of 50 and 85 (rather than 40-85), based on the lack of scientific consensus about appropriate recommendations for mammography screening intervals for women 40-49. This change in age range has not had any impact on recruitment and participation, and we expect to reach randomization and ongoing participation goals.

There has been time to take appropriate care in the development and testing of intervention materials and strategies without compromising the time allotted to the ascertainment of outcomes. The final ascertainment for appropriate breast cancer screening behaviors, including annual mammography, will occur at the 18 month follow-up. Recruitment, screening, and baseline collection materials and procedures have been finalized and implemented.

We have made contact with and placed brochures at appropriate clinics, and these clinics agreed to display information about the study (see Appendix). However, this recruitment method yielded very few interested participants (n=30). In addition, names of age-eligible participants were obtained from other FHCRC studies, and contacts have been made to approximately 700 age-eligible participants to provide information about the current study and to assess interest.

Participation based on this initial contact has been about 10% (107/700 women expressed an interest in participating). Nineteen of these women were ineligible (primarily based on previous breast cancer). Six women declined to participate. Tracking programs were developed and regular tracking reports were run and reviewed regularly during study recruitment. One additional contact was made with women on the initial FHCRC lists to encourage study participation. Additional lists are being obtained from other FHCRC studies and other appropriate sources, and community recruitment efforts (including recruitment of minority participants) are ongoing. This additional contact resulted in 140/700 women who were interested in participating in the study (15.3% response rate).

Names of age-eligible women from Department of Motor Vehicle public record lists were obtained, sorted by zip code. Specific zip code areas were targeted (e.g., based on proximity to FHCRC and increased numbers of minorities in specific zip code areas). A total of 7696 women received these mass mailings with a total number of interested responses of 387 women (5.03% response rate).

Out of 608 women expressing interest in the study, currently 350 women are participating. Thirty participants were ineligible (based primarily on age or previous breast cancer), 135 declined to participate after initially expressing interest, and individual session appointments are still being set up for 8 women. A total of 63 participants have withdrawn from the intervention (the current number of 350 participants does not include these participants); attempts are being made to do follow-up with these participants.

Baseline questionnaire booklets (Booklet 1) have been completed by a total of 316 current participants (does not include 22 returned booklets of women who later withdrew from the intervention).

**Risk Assessment runs completed and Breast Cancer Risk Appraisal Reports printed for each participant; Risk Appraisal Feedback sessions conducted**

Procedures and materials for risk assessment runs and risk appraisal feedback sessions have been finalized and implemented. The Facilitator's Manual and the Risk Appraisal Information Sheet (provided to participants at this individual session) can be found in the Appendix. The Risk Appraisal Session Checklist includes debriefing questions for the nurse counselor to complete after the session is over.

All risk appraisal sessions were completed by the end of September 1997.

**Immediate Post-Appraisal Packets mailed out and returned.**

The post-appraisal questionnaire booklets (Questionnaire Booklet Two; not included in Appendix because it contains material of limited distribution) have been finalized, printed, and implemented. Mailing and tracking strategies and programs have also been finalized. Tracking reports are being run and reviewed regularly. Immediate post appraisal packets (Booklet 2) have been completed by 275 current participants (does not include 14 returned booklets of women who later withdrew from the intervention).

**Psychosocial Group Counseling Intervention conducted with early and delayed treatment participants.**

Psychosocial group counseling intervention session materials and strategies have been finalized. The psychosocial group counseling intervention session materials and strategies have been implemented with initial participants and some review and revision of these materials occurred after initial implementation to enhance the materials' relevance and accuracy. Brief evaluations are being completed by participants after each session and a debriefing form for each session is completed by the nurse counselor to enhance the consistency of session procedures and discussions (see Appendix). Participants are given a certificate of completion at their last group session along with information about community resources (see Appendix).

All but ten groups (4 sessions each) have completed the intervention. Currently, 245 women are currently enrolled in or have completed group sessions. The remaining group sessions will take place in October 1997 and November 1997.

**3-Month Follow-Up Assessment booklets mailed out and returned.**

The 3-month follow-up assessment questionnaire booklets (Questionnaire Booklet Three; not included in Appendix because it contains material of limited distribution) have been finalized, printed, and implemented. Mailing and tracking strategies, programs, and reports have also been finalized and are being run and reviewed regularly.

Currently, 200 participants have completed the 3-month follow-up booklet (Booklet 3). This number does not include 3 participants who withdrew from the intervention.

### **Analysis of baseline risk perceptions (Specific Aim #3).**

Interim analyses of baseline risk perceptions took place in December 1996 and presented as a job candidate seminar by the Principal Investigator to FHCRC faculty in January 1997. This seminar was part of a successful application for an "Assistant Member in Public Health Sciences" appointment at FHCRC in the Cancer Prevention Research Program (effective 9/1/97).

Further preliminary analyses of baseline risk perceptions took place in August 1997 and were presented in poster form at the 1997 North American Menopause Society meeting in Boston (9/97). These analyses also formed the basis for a poster for the "Era of Hope" Department of Defense Breast Cancer Research Program conference in Washington DC (to be held 11/97).

Analysis comparing participants assigned to treatment (immediate) versus control (delayed) groups on variables of demographic information and psychosocial reactions (from baseline) show no significant differences.

Preliminary analysis of the first 269 participants shows a mean age of 62.3 years on enrollment (at the time of the individual risk appraisal session). Eighty-nine percent of the participants are Caucasian, 51.7% are married or partnered, and 86.6% have at least some college education. Thirty-two percent of these initial participants are working full-time, and 53% have an annual income of \$40,000 or higher.

Spearman's correlations between risk estimates and women's own judgments about their chances of getting breast cancer in the future (compared to other women their age) are low. Women's judgments about their own risk showed a 0.294 correlation ( $p=.0001$ ) with the Gail absolute risk estimate and a  $-0.409$  correlation ( $p=.0001$ ) with the Taplin estimate (which categorizes women into 1 of 4 risk categories, with 4 being low risk).

Thus, participants' views of their personal risk for breast cancer are generally inaccurate based on current risk estimate algorithms. Further analysis will determine the impact of the individual risk appraisal sessions on women's views of their risk for breast cancer, as well as their psychological reactions to breast cancer risk appraisal and their sense of coherence. In addition, future analyses will determine the effect of the group counseling and educational intervention sessions on study constructs and the long-term impact of the individual and group interventions on breast cancer screening behaviors.

### **Analysis of risk appraisal feedback session reactions (Specific Aim #4).**

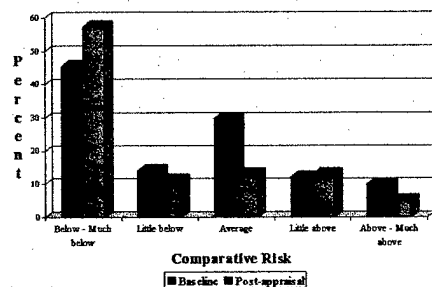
Interim analyses of risk appraisal feedback session reactions took place in December 1996 and presented at an FCHRC faculty seminar (see above). Further preliminary analyses of baseline risk perceptions took place in August 1997 and were presented in poster form at the 1997 North American Menopause Society meeting in Boston (9/97). These analyses also formed the basis for a poster for the "Era of Hope" Department of Defense Breast Cancer Research Program conference in Washington DC (to be held 11/97).

Women's judgments about their own risk showed a 0.294 correlation ( $p=.0001$ ) with the Gail absolute risk estimate and a  $-0.409$  correlation ( $p=.0001$ ) with the Taplin estimate (which categorizes women into 1 of 4 risk categories, with 4 being low risk).

Spearman's correlations between risk estimates and women's own judgments about their chances of getting breast cancer in the future (compared to other women their age) are low.

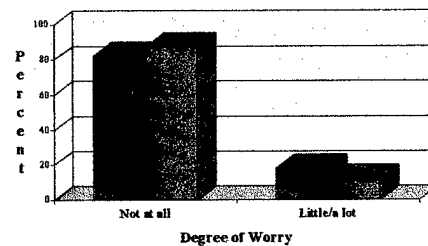
There is a downward-shift toward less threatening risk perceptions after risk appraisal.

“My risk of breast cancer compared to other women my age”



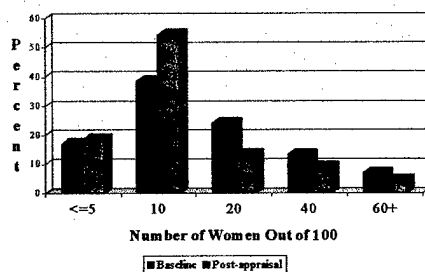
(N=246)

“Worries about breast cancer interfere w/daily activities”



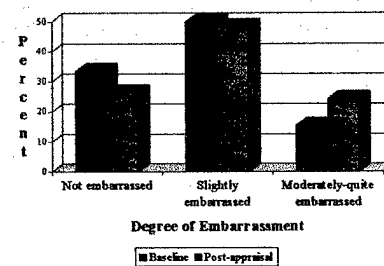
(N=247)

“Number of women I’d guess would experience breast cancer some time”



(N=237)

“Think women are embarrassed to admit they have breast cancer”



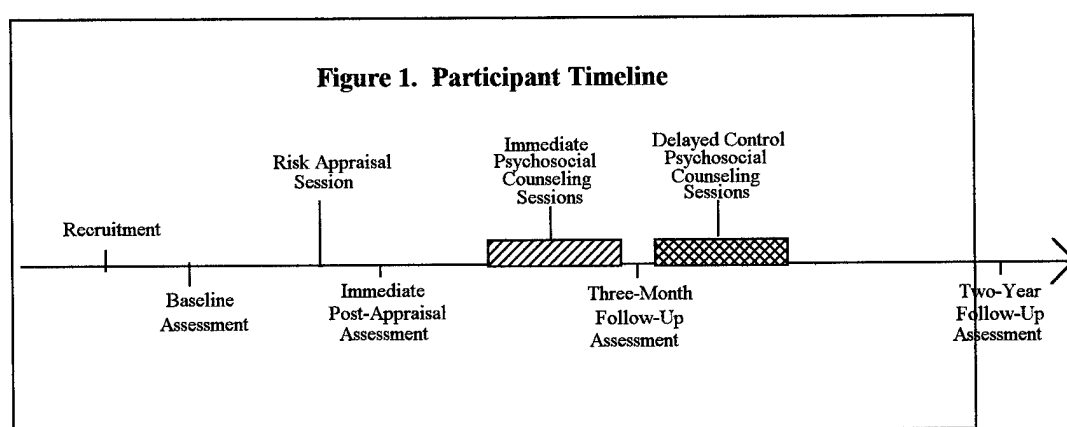
(N=247)

### **Analysis of psychosocial group counseling intervention reactions (Specific Aim #1)**

Anonymous evaluation information has been obtained regularly throughout the sessions. Formal analysis of the psychosocial reactions to the group counseling intervention (comparing treatment and control groups) will be completed in year 4.

### **Long-Term Follow-Up (18-months post-enrollment) Assessment booklets mailed out and returned.**

Assessment booklets for the long-term follow-up are being completed in year 4 with subsequent analysis of all participants' long-term responses to the individual and group intervention sessions.



**Table 1. Breast Risk Assessment Categories from Group Health Cooperative of Puget Sound**

| Risk Category            | Risk Factors   |  | Relative Risk |
|--------------------------|--|--|---------------|
|                          | <b>Women 40-49</b>   | <b>Women 50+</b>                               |               |
| <b>Level 1 (highest)</b> | Prior breast cancer, 2 1st-degree relatives with breast cancer | Same   | 4-14          |
| <b>Level 2</b>           | 1 1st-degree relative with breast cancer                       | 1 1st-degree relative or 2 minor risk factors* | 1.9-3.5       |
| <b>Level 3</b>           | ≥1 minor risk factor*  | All other women                                | 1.2-1.9       |
| <b>Level 4 (lowest)</b>  | All other women  | Not applicable                                 | 1.0           |

\*Minor risk factors: 2nd degree relative with breast cancer, early menarche (age 10), late menopause (age 55), 1st birth after age 30 or nulliparity, previous breast biopsy for benign disease. Adapted from 51



**Table 2: Timeline for Construct Measurement**

|                                   | <b>Baseline</b> | <b>Immediate<br/>post-<br/>appraisal</b> | <b>Three-<br/>month<br/>follow-up</b> | <b>Long-term<br/>follow-up</b> |
|-----------------------------------|-----------------|--|---------------------------------------|--------------------------------|
| Estimated risk                    | *               |  |                                       | <b>update</b>                  |
| Perceived risk                    | *               | *  | *                                     | *                              |
| Psychological distress            | *               | *  | *                                     | *                              |
| Breast cancer screening           | *               |  |                                       | *                              |
| Sense of coherence                | *               | *  | *                                     | *                              |
| Coping style                      | *               |  | *                                     | *                              |
| Other health-related<br>behaviors | *               |  |                                       | *                              |
| Social Support                    | *               |  | *                                     | *                              |
| Quality of life                   | *               |  | *                                     | *                              |

## **CONCLUSIONS**

### **Summary Implications of Completed Work**

Completed work in years 1 through 3 has focused on start-up, development activities and implementation of the intervention and data collection procedures (with careful attention to ensuring that materials and strategies are accurate, appropriate, and acceptable to age-eligible women). Quality assurance procedures (including tape-recording, debriefing forms, and weekly team meetings are in place to ensure consistency in procedures.

Minimal revisions to the intervention, based on the initial implementation experience, have informed subsequent intervention efforts. Recruitment activities are completed and multiple approaches to community-based recruitment were implemented to ensure adequate exposure to information about the study for potential participants.

Careful attention has also been focused on the short-term nature of the intervention and strategies to assure its integration into participants' lives over the long-term. Focus groups conducted about both health information materials and group counseling strategies have helped guide the intervention. Based on this information, health information pamphlets have been obtained to provide some basic women's health information in addition to breast cancer and breast health information. Guidelines, memos, and team meetings have been held regularly for the nurse counselors to discuss questions that have come up as well as to turn group members and the session discussions back toward the primary focus of the study--breast cancer and breast cancer screening.

### **Recommended Changes to Future Work to Better Address Problems**

The year 1 effort toward development and start-up meant that efforts in year 2 and beyond have been stepped up to ensure that study timelines are met. Initial year 3 activities will be specifically focused on ensuring adequate numbers of participants are recruited during the final recruitment push while at the same time maintaining the flow of participants through the individual and group intervention sessions. Data cleaning procedures are being implemented and preliminary data analyses will be programmed and carried out to provide initial descriptions of the study sample and to inform future analyses.

Although the start-up and development timeline was extended to enhance the intervention, it is anticipated that we will reach randomization goals by October 1997 and will have 300 to 350 participants continuing with long-term follow-up. We also anticipate that we will obtain the appropriate data for study analyses within the revised timelines identified below. Final analysis will be completed within the grant period, based on the shift in age eligibility and the need to ascertain outcomes of annual (versus biannual) mammograms. Testing of hypotheses corresponding to Specific Aims shows an extended duration to more accurately incorporate the final analytic phase (i.e., last six months) of the funding period that will include further analyses of these data. A revised Statement of Work is being submitted through the appropriate channels.

#### Statement of work for year 4:

During year 4, most study efforts will focus on completion of the group intervention, follow-up packet mailing, coding, and data entry, analyses, and preparation of the final report.

- 14 to 25 months: Recruitment and screening of participants; Baseline Assessment booklets mailed out and returned.
- 15 to 26 months: Risk Assessment runs completed and Breast Cancer Risk Appraisal Reports printed for each participant; Risk Appraisal Feedback sessions conducted
- 16 to 26 months: Immediate Post-Appraisal Booklets mailed out and returned.
- 18 to 28 months: Psychosocial Group Counseling Intervention conducted with early and delayed treatment participants.
- 20 to 29 months: 3-Month Follow-Up Assessment booklets mailed out and returned.
- 24 to 48 months: Analysis of baseline risk perceptions (Specific Aim #3).
- 26 to 48 months: Analysis of risk appraisal feedback session reactions (Specific Aim #4).
- 30 to 48 months: Analysis of psychosocial group counseling intervention reactions (Specific Aim #1)
- 36 to 47 months: Long-Term Follow-Up (18-months post-enrollment) Assessment booklets mailed out and returned.
- 42 to 48 months: Analysis of impact of interventions on screening behaviors (Specific Aims #2 and 5). Final data analysis and preparation of final report.

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## APPENDIX



## Recruitment Letters



FRED  
HUTCHINSON  
CANCER  
RESEARCH  
CENTER



## Breast Cancer Awareness Program

---

November 20, 1996

«name»  
«address»  
«citysz»

Dear Ms. «lname»:

I am writing to tell you about an exciting new study for **women between 50 and 85 years of age who have not had breast cancer**. The study is being carried out at the Fred Hutchinson Cancer Research Center. In the past, you have indicated to researchers here that you might be interested in participating in other cancer prevention projects. The purpose of this study is to help women learn about their risk for breast cancer and help them learn about managing their risk.

If you decide to join, you will first be provided with an estimate of your risk for developing breast cancer, based on the latest cancer research findings. You will then participate in four group sessions at our study center downtown. At these sessions, you will learn about breast cancer and its risk factors, prevention and screening for breast cancer, and ways of dealing with any worries or concerns you might have about your risk for breast cancer. Four times during the course of the study, you will be asked to answer questionnaires about your health, thoughts, and feelings.

If you would like to learn more about this important study, please leave a message at the study office at 667-5283. A study interviewer will get back to you within a week to give you more information and, if you would like to participate, send you the first packet of questionnaires and schedule your personal risk appraisal session. Your risk appraisal, group sessions and parking are provided at no cost to you.

We appreciate your interest in breast cancer research and look forward to hearing from you!

Sincerely,

Barbara Cochrane, RN, PhD  
Principal Investigator  
Phone: (206) 667-6814

December 2, 1996

«FName» «LName»  
«saddress»  
«city», «state» «zipcd»

Dear Ms. «LName»,

Would you like to know more about breast cancer risk and prevention? Do you ever wonder about your own risk of breast cancer? We are beginning the final recruitment for an important research study at the Fred Hutchinson Cancer Research Center. The Breast Cancer Awareness (BCA) program helps women learn more about their risk for breast cancer, based on the latest research findings..

Several months ago I sent you information about this program for **women 50 to 85 years of age, who have not had breast cancer**. I am now sending a brochure, before the program ends, in case you are interested in participating sometime in the next six months. In the past, you have indicated to researchers here that you might be willing to participate in other cancer prevention projects.

If you decide to join, you will receive a personalized estimate of your breast cancer risk and participate in four group sessions at our study center downtown. At these sessions, you will learn more about breast cancer, its risk factors, prevention and screening, and how to deal with your concerns about your breast cancer risk. Four times during the study, you will be asked to answer questionnaires about your health, thoughts, and feelings.

If you would like to learn more about this study, please return the enclosed postcard or leave a message at the BCA office at **667-5283**. A study interviewer will call you within a week to give you more information and, if you would like to join, schedule your personal risk appraisal session and send you the first questionnaire packet. Your risk appraisal, group sessions and parking are provided at no cost to you.

We appreciate your interest in cancer research and look forward to hearing from you!

Sincerely,

Barbara Cochrane, RN, PhD  
Principal Investigator

## Informational Brochure

## Questions? How Do I Join the Study?

If you think you would like to participate, either complete the postage-paid reply card and drop it in the mail, or call us at 667-5283 and leave your name and telephone number. One of our interviewers will then give you a call within the next few weeks to tell you about the study and schedule a meeting with the nurse counselor.

37 We hope you'll join us!

---

Breast Cancer  
Awareness Program  
1730 Minor Ave., MP-1002  
Seattle, WA 98101  
(206) 667-5283

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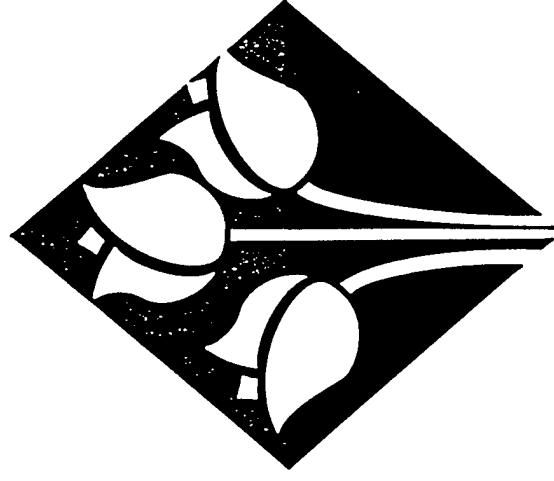


FRED  
HUTCHINSON  
CANCER  
RESEARCH  
CENTER

## What Do I Need to Know About Breast Cancer?

- 1) *Most women never get breast cancer.* In fact, almost 90% of women will *never* develop this disease.
- 2) *Most women who do get breast cancer survive.* In fact, three out of four women who get breast cancer *do not* die from the disease.
- 3) *Breast cancer is primarily a disease of older women.* Only 20% of breast cancers occur in women under age 50. The most common ages at which women develop breast cancer are their late sixties and older.
- 4) *Early detection can save your life.* The single most important factor in whether or not a woman survives breast cancer is how big the cancer is when it is found. This means that by practicing methods of early detection you have some control over surviving a breast cancer experience.

## Breast Cancer Awareness



## Learning About Your Risk

## What is the Breast Cancer Awareness Program?

The Breast Cancer Awareness Program is a new research study at the Fred Hutchinson Cancer Research Center designed to help women like you learn more about:

- Breast cancer and its risk factors
- Your own personal risk for developing breast cancer
- Early detection and screening for breast cancer
- Ways of dealing with worries about developing breast cancer
- The latest research on breast cancer prevention

If you are 50 years of age or older and have never had breast cancer, we invite you to join the Breast Cancer Awareness Program!

## What Will I Be Expected to Do?

If you decide to participate, you will be asked to:

- Meet with our nurse counselor, who, based on the latest cancer research findings, will give you information about your personal risk for developing breast cancer
- Participate in four group sessions held at our study center downtown
- Complete study questionnaires about your health, thoughts, and feelings at four times during the study:

- 1) Before your personal breast cancer risk session
- 2) At the first of the four group sessions
- 3) After the last of the four group sessions
- 4) Two years after your participation in the group sessions

## What Happens During the Group Sessions?

During the four group sessions, you will meet with a nurse counselor and 8-10 other women to increase your awareness and learn more about your risk of breast cancer.

Specifically, you will learn about risk factors for breast cancer, early detection and screening, and ways of coping with concerns you may have about developing breast cancer. The sessions, which last for about two hours each, will meet once a week for one month.

All of the counseling and group sessions are free-of-charge, and free parking and refreshments will be provided.

## Letter to Providers

Mena Hippert  
1101 Madison Suite 1150  
Seattle, WA 98104

Dear Ms. Hippert,

I am writing to tell you about an exciting new study, Breast Cancer Awareness: Learning About Your Risk, being carried out at the Fred Hutchinson Cancer Research Center that may be of interest to some of your patients between 50 and 79 years of age. This is a study about enhancing positive reactions to breast cancer risk appraisal for women. Participants will learn more about their personal risk of breast cancer and strategies for managing that risk.

Based on the latest cancer research findings, participants will be provided with a scientific estimate of their risk for developing breast cancer. They will then participate in four group sessions to learn even more about breast cancer and its risk factors, prevention and screening for breast cancer, and ways of dealing with worries or concerns they might have about this risk. Finally, they will be contacted two years after joining the study so that we can learn more about the impact of this new knowledge on their health and health practices.

We would appreciate your review of the enclosed brochure. We will be contacting you so that we can obtain your permission to place these brochures in your office for patients who might like to learn more about this important study. If you have any questions about the study, please feel free to contact one of us at the number below. Thanks for your interest in breast cancer research.

Sincerely,

Barbara Cochrane, RN, PhD  
Principal Investigator

Gretchen Zunkel, ARNP  
Nurse Counselor  
667-4095



## Brochure Placement Log

**Breast Cancer Awareness  
Brochure Placement Log**

| <b>Contact Information</b>  | <b>Initial Contact</b>   | <b>Letter mailed</b>        | <b>Phone follow-up</b>                      | <b>Mailing Date</b> | <b>Follow-up visit</b>                  | <b>Brochure #s placed</b>   |
|---|--------------------------|-----------------------------|---|---------------------|---|---|
| Pamela VanPelt, ARNP 363-4555<br>North Seattle Women's Group<br>1560 N 115th Suite 212<br>Seattle, WA 98104   | Phone contact<br>1/10/96 | Feb-96                      | 3/6 OK to place brochures                   | Mailed 3/28         |   | 100-115--3/28   |
| Mena Hippert, Clinic Manager<br>386-3400<br>1101 Madison Suite 1150<br>Seattle, WA 98104  | Phone contact<br>1/10/96 | Feb 96 and remailed<br>3/28 | 3/4 will run it by doctors--remail          | Delivered 4/15      | 4/15 Not able to speak with Ms. Hippert | 1100-1114--4/15   |
| Colae Migge 326-4123<br>Mailed to: Ramona Schaffer @<br>Diagnostic Imaging Department<br>Pacific Medical Center<br>1200 12th Ave S, Seattle, WA 98144 | Phone contact<br>1/8/96  | Feb-96                      | 3/5 OK to place brochures                   | Mailed 3/28         |   | North: 200-210<br>Totem Lake: 240-50<br>Beacon Hill: 270-80<br>3/28 |
| Dr. Ellen Lackerman 326-2400<br>Pacific Medical Center Primary Care<br>1200 12th Ave S Seattle, WA 98144  |                          | Feb-96                      | 3/5 OK to place brochures                   | Mailed 3/28         |   | 300-315--3/28   |
| Sandra Jozlowski 320-2766<br>Providence Medical Center Healthcare<br>for Women<br>1600 E Jefferson Suite 305<br>Seattle, WA 98122                     | Phone contact<br>1/8/96  | Feb-96                      | 3/5 OK to place brochures                   | Mailed 3/28         | 4/15 on a conference call               | 400-415--3/28   |
| Marcie Crist 320-3818<br>Providence MC Comprehensive Breast<br>Center<br>550 16th Ave Suite 400<br>Seattle, WA 98122                                  | Phone contact<br>1/8/96  | Feb-96                      | 3/5 OK--talk to Cori or Michael and deliver | 4/15 delivered      | Spoke to Cori 4/15                      | 500-515--4/15   |
| Radiology Clinic--spoke to receptionist<br>Providence Medical Center<br>1600 E Jefferson<br>Seattle, WA 98122   | In-person<br>4/15        |                             |   | 4/15 delivered      |   | No reply cards included--just dropped off a few brochures           |

**Breast Cancer Awareness  
Brochure Placement Log**

| <b>Contact Information</b>  | <b>Initial Contact</b>   | <b>Letter mailed</b>          | <b>Phone follow-up</b>   | <b>Mailing Date</b> | <b>Follow-up visit</b>       | <b>Brochure #s placed</b> |
|---|--------------------------|-------------------------------|--|---------------------|------------------------------|---------------------------|
| Steve Larson 292-2200 Clinic<br>Manager Seattle Women's Clinic<br>801 Broadway Suite 511<br>Seattle, WA 98122                     | Phone contact<br>1/10/96 | Feb 96 and<br>remailed<br>4/4 | 4/1 Sounds<br>good but remail                                  | 4/15 delivered      | Not available--<br>delivered | 1000-1013--4/15           |
| Molly Ramage, Manager 386-6111<br>Swedish Medical Center Family<br>Practice Clinic<br>1101 Madison Suite 200<br>Seattle, WA 98104 | Phone contact<br>1/8/96  | Feb-96                        | 4/1 OK to<br>place brochures                                   | Mailed 4/4          | On vacation<br>4/15          | 700-715--4/40             |
| Jan Grosso, Clinic Manager<br>UW Mammography Center<br>1959 NE Pacific Ave<br>Seattle, WA 98195                                   | Phone contact<br>1/8/96  | Feb-96                        | 4/1 spoke with<br>Marian Drucker<br>-OK, mail to<br>Jan Grosso | Mailed 4/4          | Spoke to her<br>4/15         | 800-815--4/4              |
| Grace Parker, RN 548-5500<br>W Women's Care Center<br>UWMC-Roosevelt<br>Roosevelt Way NE Seattle, WA 98105                        | Phone contact<br>1/8/96  | Feb-96                        | 4/8 OK to<br>place brochures                                   | Delivered 4/15      | Not available<br>4/15        | 900-914--4/15             |
| Dawn Lemcke, MD 223-7500<br>V Mason Center for Women's Health<br>PO Box 900 Seattle, WA 98111<br>Street Address?                  | Phone Contact<br>1/8/96  | Feb-96                        |  |                     |                              |                           |
| Tessa Machle 635-7250 or 223-6851<br>Virginia Mason Mammography Center<br>PO Box 900 Seattle, WA 98111<br>Street Address?         | Phone Contact<br>1/8/96  | Feb-96                        | 3/96 OK to<br>place brochures                                  | Mailed 3/28         |                              | 600-615--3/28             |

## Telephone Screening Scripts

## **Telephone Script for Recruitment Calls**

### **If you reach an answering machine:**

Hi, this is a message for \_\_\_\_\_. I'm calling from the Breast Cancer Awareness Program. We'll try to reach you again soon. If you like you can call the BCA message line at 667-5283 to let us know the best times to call. Thanks.

### **Introduction**

Hello, this is \_\_\_\_\_ from the Fred Hutchinson Cancer Research Center. I'm calling because you expressed interest in the Breast Cancer Awareness Program. Is now a good time to talk about the study?

### **Screening Questions**

Before I tell you about the project, I'd like to ask you a couple questions.

--First, what is your age? (NEEDS TO ANSWER 50 TO 85 TO BE ELIGIBLE.)

--[ONLY IF WOMAN IS FROM WHI SAMPLE:] Second, are you currently a study participant in the Women's Health Initiative? (NEEDS TO SAY NO--OF THE NAMES WE GOT FROM WHI, ONLY THE ONES NOT PARTICIPATING ARE ELIGIBLE FOR OUR STUDY. OTHER STUDIES ARE USUALLY OK.)

--Finally, have you ever been told that you have breast cancer?

(NO = ELIGIBLE, GO TO \*)

(YES = INELIGIBLE) I'm sorry but our study includes women (who are between the ages of 50 and 85 / who have not had breast cancer) so you are not eligible. We do appreciate your interest and your desire to help. If you have specific questions about breast cancer I can give you the number for the Cancer Information Service (1-800-4CANCER = 1-800-422-6237). They might also know of other studies you may be eligible for if you are interested.

Thank you for your time and your interest in breast cancer research.

\*Great! It sounds like you are eligible for our study. I'd like to tell you a little bit about the study to see if you might be interested in joining.

### **Study Description**

You might remember some of this information from the brochure, but I need to go over it so you'll understand what the program involves.

The purpose of the Breast Cancer Awareness Study is to look at breast cancer risk for women between the age of 50 and 85. If you agree to participate, you will learn more about your own personal risk of developing breast cancer and strategies for managing your risk.

First we'll mail you some questionnaires about your health, thoughts and feelings. We'll ask you to fill these out and bring them with you when you come in for your private session with our nurse counselor. She will provide you with an estimate of your risk for developing breast cancer, based on the latest cancer research findings. She'll also give you another packet of questionnaires to be filled out and returned to us.

You will then participate in four group sessions which will last about two hours each, meeting every week for 4 weeks. You would need to attend each of these four meetings. During these sessions you'll meet with a health counselor and a group of 6 to 10 other women, to discuss strategies for prevention and early detection of breast cancer, and ways of dealing with your worries or concerns. A third set of questionnaires will be mailed to you around this time, and then finally, we'll mail you a follow-up set of questionnaires in two years.

Do you have any questions about this study?

Are you interested in participating?

**IF NO:** Thank you very much for your time. We appreciate your interest in breast cancer research.

**IF YES:** I'd like to schedule your individual session, but first I need to check on your availability for group sessions. In order to participate, you need to be available for these 8 dates. You will be randomly assigned to a set of 4 of these dates for your group sessions.

[READ DATES]

Are you available for these dates?

**IF YES:**

Great, I can schedule the individual session and send you the first packet of questionnaires. Is there any time on a weekday when you would be available to come in for your individual session?

--You will find out at the individual session which 4 dates your group session will be.

--Please fill out the questionnaire before you come--we don't want your time talking with the nurse counselor about the study to be used up on the questionnaire.

--Could I confirm your address please?

**IF NO:**

We're just beginning this project, and other dates and times for the group sessions will probably be available in the future. Can you tell us when you would be able to attend the group sessions? [SAME SPIEL IF THEY CAN'T COME DUE TO LOCATION--

THERE MAY BE SESSIONS IN TACOMA, AND MAYBE EVEN BELLINGHAM.]

We'll let you know if something that fits your schedule becomes available. Thank you very much for your interest and time.

## Question & Answer Sheet for Telephone Interviewers

## BCA Questions and Answers

### Eligibility Q's

I'M IN ANOTHER STUDY--AM I STILL ELIGIBLE?

[NOTE TO THE INTERVIEWERS: The names we got from WHI are supposed to be ineligible for WHI, but sometimes that's not true, and they're actually participating. As a courtesy to WHI since they shared the sample with us, we will not recruit someone who answers yes to the WHI question at screening. But if we find out once a participant is enrolled in BCA, we don't have to drop her. Membership in most other studies isn't a problem. If the woman is in some other breast cancer study, that will have to be handled case-by-case by Barb and Gretchen.]

I DIDN'T HAVE BREAST CANCER BUT I HAD A LUMP IN MY BREAST /  
BREAST REDUCTION SURGERY / SOME OTHER NON-CANCER PROBLEM  
WITH THE BREAST:

Because this is a breast cancer risk study, we are only concerned with whether or not you have had breast *cancer* at any time. You are still eligible if you've had any other surgery or problem with your breasts that wasn't related to cancer.

I DIDN'T HAVE BREAST CANCER BUT I HAD ANOTHER KIND OF CANCER:

You are still eligible--breast cancer is the only type of cancer that would make you ineligible for our study.

### General Q's

WHO IS THE PRINCIPAL INVESTIGATOR?

The principle investigator is Barbara Cochrane, a nurse scientist with expertise in women's health and the impact of health changes on women's lives. I'd be happy to give you her number so that you could discuss any concerns you might have about the study. (Barbara Cochrane: 667-6814)

I HAVE QUESTIONS ABOUT THE STUDY.

You're welcome to call the coordinator of the study, Elise Leaf, at 667-5825. She would be glad to try to answer your questions.



## **WHO IS FUNDING THIS PROJECT?**

The US Army Breast Cancer Research Program. (In the process of downsizing the Department of Defense, some money was allotted to medical research, and it was decided that it would be easier for them to administer the funds themselves than transfer it to NIH.)

## **IS THIS PART OF THE WOMEN'S HEALTH INITIATIVE/SOME OTHER STUDY?**

[The sample of women who receive the recruitment mailing will come from a number of other studies, including the Women's Health Initiative.]

This is a separate study run by Barbara Cochrane, a nurse scientist with expertise in women's health and the impact of health changes on women's lives. We did get your name from another study as someone who might be interested in cancer prevention research, but this is a separate study.

## **WILL THIS BE CONFIDENTIAL?**

All of your individual responses on the questionnaires and your private risk assessment will be completely confidential. You would be free to share as much or as little information about yourself as you wish in the group sessions.

## **WHAT IF I DECIDE I DON'T WANT TO CONTINUE AT SOME POINT?**

You are certainly free to withdraw from the study at any time. However, it's very helpful to us if the women who join the study remain in the study throughout. If you don't think you will be able to complete the group sessions and questionnaires, you might consider whether or not you want to participate.

## **WHAT'S THE PURPOSE OF THE STUDY / WHAT ARE YOU TRYING TO FIND OUT?**

The main purpose of the study is to help women understand and deal with their own personal risk for breast cancer. We'd also like to find out what kind of impact breast cancer risk assessment has on women's lives.

## **WHAT WILL I GET OUT OF THE STUDY?**

You will get an individualized assessment of your own risk for getting breast cancer. At the group meetings you will learn about ways of dealing with this information, including techniques for early detection, for reducing your risk, and for coping with your concerns about these issues.

## **IF I'M NOT ELIGIBLE/CAN'T PARTICIPATE, WHERE CAN I GET INFORMATION ABOUT MY BREAST CANCER RISK?**

For general information about cancer risk and prevention, you can call the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). They can answer your questions and send you more information. For information about your own personal risk for breast cancer, we recommend that you talk to your doctor, or another health professional with experience in women's health.

## **Logistical Q's**

### **WHERE WOULD I HAVE TO COME FOR THESE SESSIONS?**

Both the individual risk appraisal session and the group sessions will take place in the Metropolitan II building near the Stewart and Olive St. exits from I-5. We will provide you with a map, as well as parking information, if you chose to participate. We will also give participants parking validation for the lot under the building when they come.

### **WILL I GET PAID?**

No, but you will learn about your own risk for breast cancer, and you'll get information on strategies for prevention and early detection of breast cancer. (See WHAT WILL I GET OUT OF IT?)

## **Q's about Surveys**

### **WHAT KINDS OF THINGS WILL THE QUESTIONNAIRES COVER?**

We'll ask you about your health, and general thoughts and feelings, as well as your thoughts and feelings specifically about breast cancer. Your individual responses to the questionnaires will be confidential.

### **HOW LONG WILL THE QUESTIONNAIRES TAKE TO FILL OUT?**

They'll take about 45 minutes to an hour to complete each time. But since you'll be completing them at home, at your leisure, you can fill them out all at once, or in pieces, if that is easier.

## **Q's about Risk Assessment and Group Sessions**

### **HOW WILL YOU DETERMINE WHAT MY RISK IS?**

The nurse counselor will use information from your questionnaire or ask you questions such as your age, and how old you were when you had your first child if you've had any children. These are factors that have been associated in previous research with women's risk for breast cancer. Then the nurse counselor will use a computer program to decide what your risk is, and explain to you what the results mean.

### **WHO WILL BE DOING THE RISK APPRAISAL SESSION/LEADING THE GROUP SESSIONS?**

One of the nurse counselors will be conducting the risk appraisal sessions/leading the group sessions. This would be either Gretchen Zunkel or Barbara Cochrane, [another nurse counselor will be hired soon--we'll keep interviewers posted] who are both nurses with expertise in women's health.

### **DO I HAVE TO COME TO ALL FOUR SESSIONS?**

Yes, for the knowledge you will gain, as well as for the clarity of the results of our study, you need to attend all four sessions if you choose to participate.

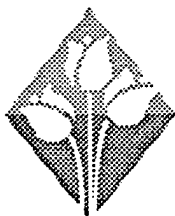
### **I'M REALLY BUSY--WHEN WOULD THE GROUPS BE?**

To start with, we are scheduling a group on Wednesday nights and Saturday mornings, but there will be other times available in the future. If none of the times available fit into your schedule, we'd like to call you back when we have more times available. (Ask what times she **could** make, record on call record sheet.)

### **HOW DO YOU ASSIGN THE GROUPS?**

Which 8 dates you're available for depends on your schedule, but we will assign which 4 of those 8 dates your group will be.

## Risk Appraisal Checklist and Debriefing Form



## Breast Cancer Awareness Program

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NC:

**Participant #**

Date

### **Risk Information Session**

Agenda for risk information session explained (consent, risk information, interview, questions and concerns, time line) \_\_\_\_\_

#### **Consent:**

- participant rights- participation is voluntary-you can withdraw at any time
- time involved- (this session plus 4 group sessions)
- receiving risk information may bring up feelings
- benefits and costs- you will receive information and group support, no cost
- confidentiality
- tape-recorded interview

Questionnaire checked for missing data \_\_\_\_\_

Consent read and signed by participant \_\_\_\_\_

Risk Information Session (Tape-Recorded in 5% of participants)  
Rapport Building Questions:

- 1. What interested you about this study?  
•  
•
- 2. Have you participated in other research studies?  
•  
•
- 3. In the past, how have you learned about breast cancer risk?  
•  
•
- 4. What is your perception of your risk?

Follow-up: depending on participant's response

don't know- Since you are here, I'll assume then that you are interested in learning more about your risk. Have you ever had a chance to talk to anyone such as a health care provider about your risk?

low risk- It sounds like it is your perception that your risk is low, have you heard about your own risk from other sources like your health care provider? yes-what have you heard? no- or Where have you gotten information regarding your risk?

middle or medium-Have you every had a chance to talk to anyone such as a health care provider about your risk?

high risk- Have you experienced breast cancer in a relative or friend? have you talked about your risk with other people like your health care provider?

Present risk information sheet and explain:

Gail \_\_\_\_\_

Taplin \_\_\_\_\_

I'd be interested to know what kinds of things you are hoping to get out of this program?

### **Questions or concerns:**

Do you have any questions or concerns?

Are there any questions that I can answer now?

(Only questions and concerns directly related to the risk information should be answered at this time)

### **Q&A participant's questions**

What are the groups like?

A: There are four sessions on risk, stress management as it relates to breast health, detection and screening, and support for healthy behaviors

What is the purpose of the study?

A: To better understand women's reactions to receiving an estimate of their risk for developing breast cancer and to a four-session intervention for talking about the feelings associated with risk

Why do you ask so many questions about thoughts and feelings?

A: We are trying to understand various aspects of your health, behaviors and feelings that you may have

Ongoing questions and concerns will be clarified in subsequent sessions. We will be starting the groups in the next few weeks and will let you know when you will start. In the meantime if you have any questions feel free to contact me at 667-4095.

**Time-line:**

After the risk discussion, explain the time line to the participant. She will be contacted when we begin the next series of groups and we will tell her exactly when her group will begin.

**Participant Assessment:**

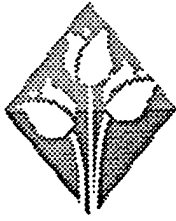
Stated response:

Other emotional response:

Any questions or concerns:

## Facilitator's Manual





## **Breast Cancer Awareness Program**

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### **Risk Appraisal Session**

#### **Overview**

The risk appraisal session is an individual session intended to inform the participant of her breast cancer risk. This session is the first in-person phase of the intervention in which the participant meets with a nurse counselor to better understand her risk information. This session will be conducted after the participant has signed a consent form indicating her participation in the study. The risk appraisal will be based on information submitted by the participant in the first questionnaire booklet. It will incorporate the Gail (Gail, Brinton, & Byar, 1989) and Group Health Cooperative (GHC), (Taplin, Thompson, & Schnitzer, 1990) models of risk assessment for breast cancer, which offer participants two views (one quantified and the other categorical) of their risk for breast cancer because the Gail model only provides risk estimates up to age 80. For women 75 and over, only the GHC model will be used to inform them of risk.

These models are intended to project individualized probabilities of developing breast cancer for women who are being examined annually. The Gail assessment model is utilized by the Breast Cancer Detection and Demonstration Project (BCDDP) and is also used widely in counseling and establishing criteria for clinical trials. The GHC model is

used by the Group Health Cooperative, a large health maintenance organization, in their Breast Cancer Screening Program.

### **Risk Perceptions**

Women who are concerned about their risk for breast cancer need information in order to seek and interpret risk information and also to make informed decisions with regard to early detection and screening. The risk appraisal session will offer the participant an individual meeting in which her risk for breast cancer is determined, as well as an opportunity to express concerns and seek clarification about the risk appraisal. Women probably overestimate or underestimate their perception of risk without accurate risk appraisal. It is thought that older women age 65 and over are especially prone to underestimate their risk of breast cancer and to ignore early screening and detection recommendations. Risk perception is thought to be a complex cognition that is influenced by knowledge, personality, and emotions as well as personal beliefs and values. Risk appraisal can provide women with risk information grounded in current scientific knowledge.

#### **Breast Risk Assessment Categories from Group Health Cooperative**

| Risk Category        | Risk Factors  |  | Relative Risk |
|----------------------|---|--|---------------|
|                      | Women 40-49   | Women 50+  |               |
| Level 1<br>(highest) | Prior breast cancer,<br>2 1st-degree<br>relatives with breast<br>cancer | Same   | 4-14          |
| Level 2              | 1 1st-degree<br>relative with breast<br>cancer                          | 1 1st-degree<br>relative or 2 minor<br>risk factors* | 1.9-3.5       |
| Level 3              | ≥1 minor risk<br>factor*  | All other women                                      | 1.2-1.9       |

|                             |                        |                       |            |
|-----------------------------|------------------------|-----------------------|------------|
| <b>Level 4<br/>(lowest)</b> | <b>All other women</b> | <b>Not applicable</b> | <b>1.0</b> |
|-----------------------------|------------------------|-----------------------|------------|

\*Minor risk factors: 2nd degree relative with breast cancer, early menarche (age 10), late menopause (age 55), 1st birth after age 30 or nulliparity, previous breast biopsy for benign disease. Adapted from Taplin, Thompson & Schnitzer (1990).

### **Participant Intake**

The nurse counselor (NC) will greet and meet the participant on the second floor of the Fred Hutchinson Cancer Research Center. The participant will be escorted to the counselor's office and offered a brief overview of the purpose of the session (to give the participant her risk information for breast cancer). A verbal summary of the consent form will be offered including a) participant rights: i.e. your participation is voluntary, feel free to talk about any uncomfortable feelings or thoughts that you are having, also, you may refuse to answer any questions; b) time involved: risk feedback (45 to 60 minutes), four group-counseling sessions (1-1/2- 2 hours), time to answer questionnaires; c) benefits and costs: you will receive information about breast cancer risk and it will involve no costs except time and travel; d) confidentiality: all of your study records will be kept strictly confidential. If you have questions you can call the nurse-counselor, Gretchen Zunkel, at 667-4095 or the principal investigator Dr. Barbara Cochrane at 667-6814.

The participant will have Packet #1 from which the NC will calculate the participant's "risk" for developing breast cancer. To maximize time efficiency, the participant will be reading the consent form while the NC is entering the data from the risk information on the questionnaire. However, the data from the risk appraisal will not be recorded until the participant has signed the consent form. Questions about the study will

be answered after the participant has thoroughly read the consent form and the NC has reviewed the consent form information. The participant will sign the consent form, the NC will witness the signing, and the participant will be given a copy of the consent form for her records.

It will be most helpful to frame the feedback so it is meaningful to the participant.

Possible scenarios for the delivery of the risk feedback:

What is your sense of your risk for breast cancer?

Participant: Don't really know- I think it is low-I think it is high

Why do you think your risk is \_\_\_\_\_?

N-C: Here is the information from the computer program about your risk based on the answers to questions that you answered in the questionnaire booklet.

Your risk percentage is about 1 in \_\_\_\_, or \_\_\_\_% and to say it another way your risk level is 1 (highest), 2 (middle), or 3 (low). If participant over or under estimates her risk it will be helpful to discuss the over or underestimation. "Why did you think your risk was high/low?"

After informing the participant of her risk information, the NC will attend to verbal and nonverbal cues of the participant's reaction to the risk appraisal. Some behaviors or affects that might be observed at this time are: fear, sadness, detachment. The participant is assured that ongoing questions and concerns will be clarified in subsequent sessions. Behaviors and reactions of the participant will be recorded on a debriefing form after the risk appraisal session.

## **Risk Appraisal Session**

### **Preparation:**

#### **Day before scheduled risk appraisal**

- check schedule of participants with ESR
- obtain phone numbers for scheduled participants
- call participants to confirm time and ask questions (directions, time commitment, etc.)

#### **Day of risk appraisal session**

1. Greet the participant on the second floor. Escort her to designated office. Offer coffee. Collect Packet #1. Review the agenda for the session including:
  - review and signing of consent form
  - her perception of risk and her actual risk information
  - asking questions and voicing concerns
  - schedule of future sessions
2. Allow participant to ask any questions she may have about the study and give her the consent form. Provide overview of consent to highlight areas of participant rights, time involved, benefits and costs, and confidentiality. Answer any questions about consent form and witness the signing of the consent form.
3. Enter woman's risk data into computer program (BCARISK). If participant is age 50-75 provide feedback on risk to age 80 (Gail model) and level of risk (GHC model). If participant is older than 75, provide GHC feedback only and use appropriate script.
4. Ask participant if she has a sense of her own risk and then use that information to frame her risk information. For example, if the participant says, "I am at risk" or "I do not believe I am at risk" because of ... the NC can respond by asking about the participant's thoughts and the meaning of the risk information.
5. Inform the participant of the risk percentages according to the risk program for Gail and GHC model. "What does this mean to you?"

#### **Age Appropriate Risk Appraisal Discussion**

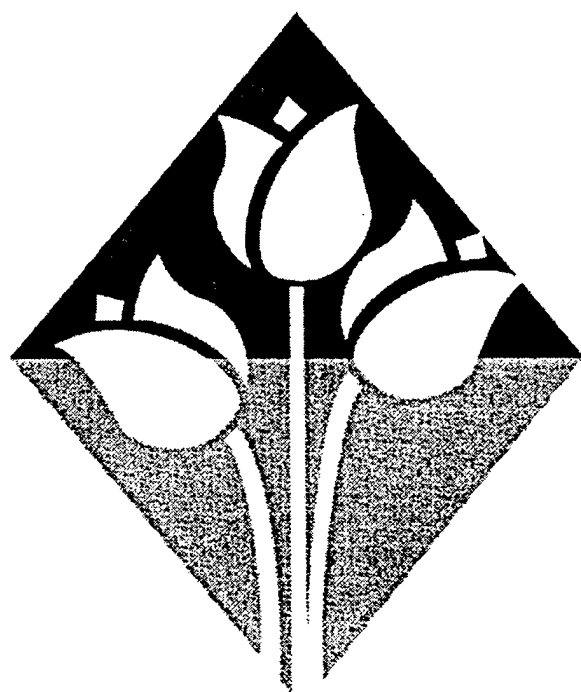
The Gail model does not account for women over 80 in delivering an accurate risk assessment percentage. Using the GHC model will provide the woman over 80 with an estimation of her risk. This woman will benefit from the intervention elements of the program. It may be necessary to tell the woman over 80 that she will benefit from the intervention and screening procedures but that few research studies have examined the screening of women over 65 (Boer, deKoning, van Oortmarssen, vander Maas, 1995; Costanza, 1994).

**Risk information for the older woman:**

- a. Breast cancer risk increases with age.
  - b. Methods to predict exact risk for women over 80 are not as complete as for younger women.
  - c. The intervention itself should provide benefit for both younger and older women regardless of risk information.
6. Explain the next steps, i.e., that woman will be assigned to a group and have her fill out the form stating her optimal times for the group.
  7. Give participant a sense of time-line for participation; we will be starting groups in the next few weeks and we will let her know. Feel free to call the NC in the meantime at 667-4095.
  8. Explain next set of questionnaires and thank participant. Also, tell her that you will look forward to seeing her at the first intervention session.

- BREAST CANCER AWARENESS PROGRAM

# **INTERVENTION MANUAL FOR GROUP FACILITATORS**



- **SESSION 1**  
**RISK**

**Begin session**

**Attendance and Recordkeeping (5 min):**

- facilitator introduces herself to group
- express appreciation for their attendance
- explain the goal of the Breast Cancer Awareness Program
  1. provide current information about breast cancer, its risk factors, and the latest screening behaviors that may help control the disease
  2. provide a forum for discussion of participant's concerns and worries and develop strategies for dealing with these feelings
  3. learn more about stress and its effect in your life
  4. make a commitment to your breast health
  5. develop partnerships for your commitment
- explain purpose and groundrules of sessions
  - mutual respect, concern for others, check-in and check-out
  - confidentiality
  - information gathering
  - develop group support- discuss our thoughts regarding our breast health which can be an uncomfortable topic but is important for our health
  - problem-solving
- fill out attendance forms (explain importance of attending all sessions)
- conduct introductory activity
- introduce topic - Risk

**Introductory Activity (10 min):**

- pair the group up by asking the following questions:
  1. What year is your car? (pair up the two with the oldest cars)
  2. How many persons were in your graduating class from high school? (pair up the two with the most persons in their class)
  3. What is the farthest place you have traveled? (pair up the two farthest travelers with each other)
  4. How many letters are in your last names? (pair up the two with the most letters in their names)
- ask participants to ask the following questions of their partner
  1. reasons for joining the study?



## SESSION 1—RISK

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- 2. benefits that you expect?
- start by asking the women to go around the table telling the group what answers their partner has shared with them

**Instruct participants on the following breast cancer and risk facts. (40 min)**

### **Breast Cancer - What we know: (Handout #1)**

- 90% of women will never develop this disease
- 3 out of 4 women who get breast cancer do not die from the disease
- 20% of breast cancers occur in women under 50 - most common late 60's and older
- early detection can save your life - by practicing methods of early detection you have some control over surviving

### **show visual aide #1 (Beti's graphic of abnormal cells vs normal cells)**

Breast cancer occurs when normal cells in the breast become abnormal and divide without control or order. These abnormal cells are cancerous and are called malignant. Breast cancer is very common and is classified in several ways depending on its location, type or size.

Terms you may of heard of:

in-situ: when cancer is found at a very early stage when it is very small usually by mammography

invasive: once the cancer spreads within the breast it is called invasive and still may be too small to feel but may be found by mammography or examination

metastatic: when cancer has spread outside the breast to other organs

### **Reasons for increase in breast cancer cases:**

- women are living longer - more likely to survive to the ages when women get breast cancer
- mammography has improved our ability to detect cancer at early stages - finding more cancers sooner
- researchers do not have all the reasons to explain the increase in cases - changes in diet, exercise, delays in childbearing, earlier age of menstruation and possible exposures to environmental pollutants may play a role and are currently being studied. to date, nothing has been proven to prevent breast cancer.

### **show visual aid #2 (graphic from risk booklet)**

This chart compares several of the major causes of death among women. Heart disease is by far the most common, causing more than 8 times as many deaths as breast cancer. However, women usually report that they are more afraid of getting breast cancer than heart disease.

*ask the group:* Why do you think this is true?

(probe: Could it be because they don't have methods to prevent breast cancer?)

# SESSION 1—RISK

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At this time we do not have all the answers to breast cancer, however, what we do have is the best information available about early detection and screening.

*ask the group:* Why is it important to know about our breast cancer risk??  
(probe: Could we prevent late stage breast cancer and possible serious side effects?)

It is through our participation in this group that we can discuss and discover ways to take advantage of the latest breast health information and screening techniques. Understanding our risk and finding out all we can about this disease will enable us to become partners in our own breast health care. We no longer have to sit on the sidelines and watch others make decisions for us. Instead, through education and sharing what we know with each other we can become a part of the process of making decisions that are right for us as individuals.

**Lifetime Risk** - is the likelihood of developing breast cancer at any time during a woman's remaining years of life.

For example: an average 30 year old has a lifetime risk of developing breast cancer of about 1 in 9. If this 30 year old reaches age 70 without developing breast cancer, her remaining lifetime risk has dropped to 1 in 16.

Another way to look at this - Suppose a woman must cross a busy street once a year; there is a chance she will be hit by a car. A younger woman's risk is higher than that of an older woman's because the younger woman probably has more years ahead. So over the years the younger woman will cross the street more times than the older one. The older woman has crossed the street successfully without incident for many years and are no longer at risk for street crossings that have passed.

**Short-term Risk** - is the likelihood of developing breast cancer in the next 1,5, or 10 years rather than the rest of the person's whole lifetime. Short-term risk increases as a woman ages because breast cancer is mostly a disease of older women.

For example: as a woman gets older her lifetime risk decreases but her short-term risk increases because of her biological changes.

Let's look at the street-crossing again. If you assume younger women can react faster and have better eyesight than an older woman, the younger will be at less risk of being hit during one trip across the street. So, although the lifetime risk of breast cancer is higher for the younger women than for older, for a given year or street crossing, the risk is lower for the younger than the older.

**Risk Factors** (which by now you can not change):

- age
- family history
- starting menstrual periods before age 12

## SESSION 1—RISK

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- having your first child after age 30
- never having a child
- beginning menopause after age 55
- atypical hyperplasia - a non-cancerous breast abnormality found by breast biopsy
- past history of breast cancer

### **Potential Modifiable Risk Factors** - inconclusive at this time

Diet, alcohol, and obesity are all in the same category- they may be important factors although their role has not been conclusively established

- alcohol: what is the link between breast cancer and alcohol? (some studies have reported a relationship, others have not-in other words, it has not been consistently reported) how much alcohol is thought to put a woman at risk? (it appears that more alcohol puts a woman at higher risk and reports vary as to what amounts place a woman at risk- the range is from 1/2 to 3 + drinks) how does alcohol cause cancer? (carcinogens in alcohol, change in estrogen metabolism, melatonin secretion) what types of alcoholic beverages? (we are not sure)
- overweight: is there a link with body size? (overweight people have higher circulating plasma levels of estrogen and this may provide a link but it is inconclusive; some studies have shown that breast cancer risk is definitely increased with overweight; differs pre and post menopause and by stage of cancer; maintaining a stable, non-obese body weight is preferable)
- diet: is there a link with diet? (in countries where they have extremely low-fat diets, the incidence of breast cancer is much lower, the problem is that we would have to cut fat intake in half to achieve a major difference; at this point eating less fat and more broccoli is probably the best that can be done)
- coffee: is there a link with coffee? (coffee has been linked with breast pain and lumpiness but probably has nothing to do with breast cancer)

Increasing the level of estrogen is thought to affect the risk of breast cancer so that oral contraceptives and hormone replacement therapy may play a part

- oral contraceptives: (having been on the "pill" for many years starting in adolescence may contribute to increased risk)
- hormone replacement is there a link with hormone replacement therapy? (women already at high risk may face a higher risk on ERT, studies have been controversial but current thinking is that only long-term hormone replacement therapy is thought to increase risk; on the positive side it decreases the risk of heart disease)
- exposure to ionizing radiation:
- pesticide and other chemical exposures
- physical inactivity: (some studies have shown that exercise may be protective)
- induced abortion

ask the group if they have any questions regarding risk factors

(probe: Do any of these risk factors surprise you? or Are there other factors that you thought were risks?) (bumping, bruising and tight bras do not cause breast cancer; it may be linked to a high fat diet)

# SESSION 1—RISK

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It is important to understand that many many women who develop breast cancer have none of these risk factors. An example of how a woman's risk for breast cancer is increased because of certain risk factors is as follows:

Think about a 50 year old woman at average risk. Her chance of developing breast cancer in the next 10 years is a little more than 1 in 50. If her risk doubles because of several risk factors, her chance of breast cancer within the next 10 years increases to 2 in 50. So even though her risk has doubled, her chance of developing breast cancer is still quite small.

## Group Discussion (15 min)

- pass out blank paper
- ask the group the following questions and ask them to write down their answers
  1. The one thing that comes to mind when I hear the words breast cancer is... (i.e. not raising my children, losing a breast, painful treatment for cancer)
  2. What women in my life have been affected by breast cancer?
  3. What emotions did I feel when I found out about their breast cancer?
  4. How would I describe my breast cancer risk?
  5. What are some of the ways I cope with these emotions?
- ask each participant to share their answers with the group

## Activity (10 min) (*Handout #2*)

- pass out Life Qualities Handout and index cards
- tell them to circle 5 life qualities from the list that they consider the most important to them right now
- ask them to write their 5 qualities on the 5 index cards
- ask them to hold the cards in front of them like a hand of cards
- use the script below and ask them to "give up" one of their 5 cards at each decision point

### Life Quality Script:

I am going to tell you a story. You are on a plane, flying over a jungle. The plane develops engine trouble and needs to put down. However, there is no break in the jungle and the situation looks bad. At the last minute the pilot sees a break and sets the plane down safely. Now that you are on the ground, you realize that the plane cannot take off again because there is not enough open space to gain speed. You have no food or water on the plane and its getting dark. All of a sudden a native appears and says that he knows of a village close by where you can get food and shelter. He will lead you there, but it will cost you one of your life qualities. Which one are you willing to give up? (*pause*)

At the village, there is food available for you to eat, but it will cost you another life quality (*pause*).

There is a place for you to sleep, but it will cost you another life quality (*pause*).

# SESSION 1—RISK

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The next morning, a car arrives (note this is a very progressive village) to take you back to civilization, but it will cost you one of your last life qualities, which one will you select (*pause*)?

- explain the point of the story - the last life quality they hold in their hands is probably the one they hold most valuable at this point in their lives
- ask participants to think about how well their work or personal lives provide opportunities to achieve their “most important life quality”
- explain that stress such as risk anxiety and how we deal with that stress can interfere with what is most important to us
- explain that through the next 3 sessions participants will have opportunities to identify ways that they can increase their “most important life quality in their personal or work-related lives.

## **Discuss: content of next sessions (5 min)**

- breast cancer screening - discussion of methods for early detection including the latest training in breast self-examination
- stress - discussion of how stress affects the body and how relaxation techniques may enhance cellular immune function
- social support - discussion of how social support can improve health and well-being
- working together as a group, helping each other with a lifetime breast health program

## **End session (5 min)**

- review date and topic of next session
- pass out evaluation
- validate parking

- **SESSION 2**

# **STRESS**

## **Begin session**

### **Attendance and Recordkeeping (5 min):**

- fill out attendance form
- questions or concerns from last session
- introduce stress topic - Our topic today is “stress” which is a topic we all know a lot about. Let’s talk about this topic by considering some hypothetical stories called “friends in need stories” and then have a chance to relate these to your own life:

### **Introductory activity (20 min):**

- pair up into 3 small groups
- pass out friends in need stories
- assign each group “a friend in need story” to work on
- explain that they should identify the areas of the friend’s life that may be stressful
- read all stories out loud and ask each group to share their ideas with the larger group

### **Friend A (*Handout*)**

A friend you have not seen since school has just finished catching you up on her life. She has recently received a raise at her job that is well deserved since she works a 60- hour week. She lives for her work and has very few outside interests. Last week you persuaded her to see her doctor regarding the breast lump she found while showering. Her doctor has recommended that she have a biopsy of the lump. She reports that she is planning on having the surgery when she can fit it into her schedule. “Right now I am under important deadlines at work and there is no one to take on the responsibility but me,” she says. “Besides what if it’s cancer-all that surgery and chemo. What if I can’t keep up with my new job?” she adds. “I can’t possibly think about it right now,” she says.

Identify the areas of your friend’s life that may be stressful for her.

### **Friend B**

A friend you haven’t seen since school has just finished catching you up on her life. She spends most of her time during the week caring for her grandchildren while her daughter works. She feels so tired at the end of the day but is determined to actively accompany her husband with his retirement agenda. Her husband is an avid fisherman and likes to travel in their motorhome on weekends. She rarely thinks about her own health and can’t remember the last time she has had a mammogram. “My family has always come first even if it means

## SESSION 2—STRESS

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my needs come last," she says. "I worry all this commotion in my life will affect my health but what choice do I have? I don't have the time to have a breast check-up anyway," she admits.

Identify the areas of your friend's life that may be stressful for her.

### **Friend C**

A friend you haven't seen since school has just finished catching you up on her life. She is married, has a part-time job and spends a lot of her free time in volunteer activities. Her doctor reported to her that her mammogram showed some changes in her breast and that she needs another mammogram in 6 months. "I must admit I worry about having breast cancer almost every day ever since I had that mammogram. I've been short-tempered with my husband and children a lot lately," she says. "I'm so confused as to what this all means and my husband tries to help but he can't possibly know what it's like to lose a breast," she adds.

Identify the areas of these friend's life that may be stressful for her.

What parts of the friends lives do you identify with?

Think to yourself for a minute how we each have different stressors in our lives that affect us.

What issues in each "friends" story affects most women at some time in their lives?

How can women learn to get their own needs met and perhaps decrease the stress in their lives?

### **Instruct participants about stress facts (45 min):**

Now that we have identified where the stress is coming from, the next step is to talk about how stress affects our body in both positive and negative ways.

### **Discuss the definition of stress**

Stress is defined as a response by your body to any demand made upon it. Your body responds to stress in many ways:

- hormones like adrenaline surge through your body.
- your heartbeat and blood pressure increases.
- your blood sugar rises.

These physical responses have helped humans to survive for thousands of years by helping them run away faster or fight harder. This is why we call our body's reaction to stress the "fight or flight" response.

Most people think of stressors, or things that cause stress, as negative, such as traffic, a difficult job or divorce. If you are not able to let off steam and relax, these effects can be

## SESSION 2—STRESS

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harmful. There is evidence that stress can sometimes weaken the immune system. The hormones cortisone and adrenaline released in response to stress do suppress the immune system. In fact, they are sometimes prescribed for disorders in which the immune system is overactive -- conditions like allergies and autoimmune diseases.

But stressors can also be fairly positive experiences like having a baby, the holidays or completing a satisfying project. Many people function best while under a certain amount of stress. Stress is like body temperature: too low or too high may be unhealthy, but the right balance can keep you going strong. It makes sense to use stress energy positively, to meet life's challenges, experiences and goals.

Whether stress is negative or positive, during periods of stress, take care of yourself by getting plenty of rest, eating healthily, exercising and relaxing without alcohol or drugs. Help your body to recover from all stress, even when you feel satisfied or excited.

Turning Stress Into Opportunity -- you cannot always choose your destiny in life or control all your stress, but you can have some control over how you react to the stress.

### **Taking charge:**

- get organized
- decide what is important then do it
- choose work that is personally meaningful

Good Coping Techniques - write down worries, set them aside and at an appropriate time go over them and find solutions. Focus on doing an exercise that takes concentration.  
**(Handout #3)**

### **Letting Go:**

- no one is immune from the curves life can throw at us, react to these curves by using it to help you go where you want to go
- openness to change can actually increase your sense of control
- if you cannot choose, make the best of the work you have been given
- learn not to waste time on things that do not matter

Good coping techniques - reading, hot baths, doing crossword puzzles.

**How do people take charge of their stress or how they can manage the stress when they cannot take charge. (Handout #4)**

**Explain:** to the group that you will now discuss stress management techniques and instruct them to think about which techniques may be helpful for our 3 friends and for each of them.

### **Stress Management**

Major work and life changes are common. Whether these changes are welcome or unwelcome, all can be stressful unless we learn how to adjust to them. Taking time to recover, refocus and regenerate following life changes can help us survive and even thrive.



## SESSION 2—STRESS

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**Recover** - regaining a sense of balance by stepping back from the situation

- plan a weekend getaway
- go to a movie
- exercise
- share your feelings

**Refocus** - take a good look

- take time to review what has just happened
- think about why it happened and what it might mean
- sort out your feelings by talking to trusted people

**Regenerate** - all change is stressful

- get extra rest
- avoid alcohol
- increase your circle of support
- eat properly

**Other stress management techniques:**

**Relaxation exercises** - demonstrate some simple stretches

1. neck roll - stretch your right ear to your right shoulder, keeping your left shoulder pulled down. Roll your head down so your chin is on your chest. Continue on to your left side. Do rolls from side to side. Begin with 8.
2. pick fruit - with one hand, reach up as if you were picking an apple from a tree slightly ahead and far above you. go from one arm to the other, building up to 8 times on each side.
3. standing body roll - let your head roll forward until your chin is on your chest. Keep rolling down as your knees begin to bend. When your hands are hanging near your knees, rest there a moment and slowly roll back up. Work up to 10 times.

**Explain to the group that relaxation exercises may be helpful to friend A and ask them to discuss ways she could include them during work hours. Ask the group to try these exercises. (5 min)**

*Play a few minutes of a relaxation tape* - point out that friend A or anyone could use these techniques. **(5 min)**

Discuss how this friend could recover, refocus and regenerate herself. **(5min)**  
How would you do that in your own life?

**Exercise as a stress management tool**

**Purpose:** Exercise is a great management tool that can meet your body's needs in times of stress. That's because stress triggers the "fight or flight" response. Exercise helps your body deal with the physiological changes that gets your body revved up.

## SESSION 2—STRESS

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Types: Walking, cycling, swimming and dancing are some of the best exercise choices. Taking a brisk 10 minute walk outside will ease tension and put your mind in a better mental state for dealing with the demands of life.

**Explain to the group that a walking exercise may be helpful to friend B and ask the group to discuss ways she could include walking in her daily routine. Discuss how this friend could recover, refocus and regenerate herself.**

### **Other stress management tools:**

- Laughter - researchers have shown that laughter increases relaxation. Muscle tension remains low for up to 45 minutes after a session of vigorous laughter.
- Meditation - an ancient technique in many Eastern traditions for coping with daily stress.
- Visualization - 2 to 3 minutes of guided daydreaming can help you to relax.

**Ask group what stress management techniques they have found useful.**

### **Positive Self-Talk**

Research has shown that most illnesses, including headaches, backaches and heart disease, can be influenced by our feelings and stress levels. When we experience life changes-positive or negative-our bodies need time to recover. Having an optimistic attitude can help speed recovery and may even keep you healthier than someone with a negative or pessimistic attitudes.

- find a role model - Do you know of a person who is good at finding information or networking? Watch how she goes about asking for what she needs.
- curb your inner critic - try not to fill your head with negative thoughts like "If I ask that question, my doctor will think I am dumb."
- practice affirmations - say short positive and motivating statements out loud like "I feel healthy today or I am a caring person".
- give yourself permission to get what you need - no question is stupid; develop information strategies. For example, many people feel intimidated in the doctor's office - they are not sure what questions to ask or forget their questions when they are ready to ask them. Some good strategies include:
  1. Develop a question sheet that will remind you of important questions to ask and write down the answers to your questions so you can think about the answers when you are at home.
  2. Bring a friend or family member to go with you to the doctor, to take notes and help you recall what was said.
  3. Bring a tape recorder and record the discussion you have with your doctor or specific teaching instructions that are give.
  4. If there is limited time or explanations seem confusing, ask for a referral to another information source.

**Explain to the group that friend C may benefit from positive self-talk (probe: Is she telling herself every day she has cancer? What could she say instead?) Ask them to**

## **SESSION 2—STRESS**

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discuss how she would find out more information about what the changes in her breast mean.

Discuss with the group other strategies for information gathering. Show the handout on breast cancer resources emphasize the Cancer Information Service, 1-800-4-cancer. Discuss how this friend could recover, refocus and regenerate herself.

**End Session (5 min)**

- pass handout (*Handout #5*)

- **SESSION 3**

# **BREAST CANCER SCREENING**

## **Begin Session**

### **Attendance and Recordkeeping (5 min):**

- fill out attendance form
- brief introductions to refresh people's memories
- questions or concerns from last session
- introduce topic-breast cancer screening

### **Start Introductory activity and warm-up exercise (5 min):**

- pass out fortune cookies and a small slip of paper and pen
- ask participants to open their fortune cookie (may eat them if they wish) and write down one question on the slip of paper regarding the topic in their cookie: mammography, clinical breast exam, breast self-examination
- place questions in a basket, mix them up and start reading the questions one by one aloud
- ask participants if there are other questions they may have and write those down as well (separate questions into 3 piles, one pile has all the mammography question, another has the clinical breast examination questions and the last pile has the breast self-examination questions)

**Instruct participants about breast cancer screening facts (40 min):** Now let's set aside these questions you have and talk about each detection method. After I have talked about each method, I will refer to the questions you have asked. Feel free to ask more questions as we go along.

**show visual aid #1** (3 photos of women demonstrating the 3 methods of detection)

The best way to detect early stage breast cancer is to participate in a Breast Cancer Screening Program which consists of:

- mammography (x-ray of the breast)

## SESSION 3—BREAST CANCER SCREENING

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- clinical breast exam (exam by physician or nurse practitioner)
- breast self-examination (BSE)

These screening tests for breast cancer are the generally-accepted methods for detecting breast cancer at early stages. At this time we cannot prevent breast cancer but we do know that if the cancer is detected early women can survive this disease and lead normal lives.

### Screening Reduces Mortality

- early detection results in a 90% survival rate
- programs using mammography and physical examination every 1 to 3 years reduces breast cancer deaths among women ages 50-70 by approximately 40%
- women over 50 are the most likely to benefit from early detection of breast cancer but are the least likely to have the necessary test
- a recent WA state survey showed 80% of the women in this state 40 and older have had a mammogram

### Advantages and Disadvantages of Screening Tests

**Mammography** - effectiveness has been proven in 5 worldwide trials (*Handout #6*)

#### Advantages :

- it allows detection of early stage breast cancer before it can be felt which may give a woman a 2 year head start on treating the disease
- allows a woman more treatment choices and better chance of a cure
- to date is the best screening test

#### Disadvantages:

- 10 to 15% cancers are missed because some tumors do not absorb radiation needed to show up in a film and because fibrous breast tissue does not show up as well as fat tissue.
- quality can be compromised by the age of the woman (this test works best in older women who generally have less fibrous tissue in their breasts), the technique and positioning during the procedure (breasts need to be flattened firmly against the plate) and the expertise of the radiologist who reads the film (facilities should be ACR accredited).
- 5 to 10% of the time results may say it is suspicious of cancer when it's not

The ACS recommends that women over 50 should have a mammogram every yr.

### Insurance coverage for Screening Mammography

- WA state mandates reimbursement for screening mammograms by 3rd party insurance every year when recommended by a health care provider.
- Medicare pays up to 80% for a screening mammogram every 2 years.

## SESSION 3—BREAST CANCER SCREENING

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**Clinical Breast Examination** - effectiveness has been proven

Advantages:

- test can be done with other health care procedures like pap tests or physical examination
- it may detect 8-10% of cancers that are missed by mammography

Disadvantages:

- effectiveness may vary with the skill of the examiner and the type of breast tissue (dense fibrous tissue is difficult to examine)
- the average size lump detected is > 1cm

ACS recommends that women over 40 should have a clinical breast exam every yr.

**Breast Self-Examination** - effectiveness in reducing mortality has never been proven. However, recent research suggests that by examining your breast on a regular basis in a thorough manner may increase your chances that this detection tool will help you detect early stage breast cancer.

Advantages:

- no cost, convenient self-care practice
- other screening tests are not 100% effective
- enables women to become partners in their own breast health protection

Disadvantage:

- women often forget to practice
- lack the necessary skills to perform a quality exam that would detect small lumps (Women who are not trained properly and do not examine their breasts regularly on average detect lumps over 3 cm. However, women with expert training and consistent practice can detect lumps less than 2 cm.)

ACS recommends that women over 20 should self examine every month

**Discuss some of the fortune cookie questions that were identified earlier by the group**

### **Breast Self Examination Training**

Purpose:

To enable a woman to take care of her own breast health by noticing any monthly changes. BSE done consistently and correctly can enable a woman to be sensitive to changes in her breast that may not be found by mammography or an exam done by her provider. But before I talk about the details of how to practice breast self-examination, I will show you a video which demonstrates entire exam.

## SESSION 3—BREAST CANCER SCREENING

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### *show video (5 min)*

BSE is generally accepted as a supplement to, not as a substitute for, mammography and clinical breast exam. Recent BSE studies suggest that the practice of quality BSE may be important in finding smaller lumps or early stage breast cancer.

Quality includes:

- coverage of the entire breast
- correct palpation technique (firm pressure, fingerpads, massaging motion, vertical strip pattern preferred)
- 3 position examination

### *show visual aid #2 (anatomy of the breast)*

#### **Discuss anatomy of the breast**

**Ribs:** The breast lies between the 2nd and 6th ribs. The ribs extend across the chest and may feel like hard ridges.

**Muscle:** Two muscles cover the ribs and lie underneath the breast. These muscles aid in arm movement. Pain in the breast is usually due to overusing these muscles.

**Ligament:** There is a ligament under each breast that supports the breast. It may feel like a thick shelf or ridge.

\*All breasts are made up of the same tissue but they may vary in size or shape. This tissue changes throughout a woman's life due to menstruation, pregnancy and menopause. As a woman experiences menopause the texture of her breast begins to remain the same from month to month. It is normal for a woman to have one breast slightly larger than the other.

**Glandular tissue:** There are 20 lobes in each breast that contain milk-producing sacs. These lobes connect to ducts that transport the milk to the nipple. These ducts may feel stringy or granular. Almost all breast cancer develops in the lobes and ducts of the glandular tissue.

**Fibrous tissue:** This tissue supports and connects the glandular tissue. It is prominent in the upper outer area of the breast. It may feel firmer than glandular tissue and moveable.

**Fat:** Each breast has a protective layer of fat. This fat is like fat you see on a chicken. It may feel soft and spongy.

### *show visual aid #3*

**Coverage of the Breast** - This diagram illustrates why complete coverage of the breast is important. As you can see, breast cancer is not confined to one area of the breast.

- upper outer area of breast - 50% of all breast cancers (most glandular tissue)

## SESSION 3—BREAST CANCER SCREENING

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- lower inner area -breast cancer in this area is less likely but is believed to be more severe

### ***Show breast models (10 mins)***

#### **Purpose of breast models:**

By practicing the proper technique on a breast model, you can sense what it like to find an abnormal change in the breast. Abnormal tissue can be any shape and is usually fixed. Although, the breast models represent what a change may feel like, you are still looking for changes in your own breast. You are becoming familiar with your own breast tissue by comparing your breasts from one month to the next.

#### **Demonstrate proper palpation technique on model**

- use the flat pads of the fingers not the fingertips
- use firm pressure to compress the breast tissue against the muscle so all deep tissue is reached.
- use a consistent massaging pattern in order to move the tissue for inspection and comparison.
- use pressure over the nipple area and after examining the entire breast, gently lift and squeeze the nipple for discharge. Note: Some women have clear discharge throughout their lives and this kind of discharge is normal. All bloody or colored discharges, however, should be reported to your health care provider.

*Pass around the models to the group and encourage women to practice palpation technique while you demonstrate the 3-step procedure*

### **Demonstrate 3-step procedure**

Step 1: Stand before a mirror with arms at your sides. Turn from side to side. Look at both breasts for anything unusual such as swelling or dimpling of the skin. Next raise your arms overhead, turn from side to side. Look again for any changes in the shape of your breast. Then rest palms on hips and press down. This will tighten your chest muscle and emphasize any changes. Turn side to side and look again.

Step 2: Raise your left arm above your head and with right hand examine your left breast. Begin your exam below the collarbone and use the pads of your 3 middle fingers of your right hand. Press firmly, massaging the breast in a set way until the entire breast has been covered. You can choose a circle or up and down pattern. Larger breasted women may want to use the up and down pattern for better coverage. Repeat the exam on your right breast using your left hand. Remember how the parts of the breast feel while checking for any hard knots or thickening.

Step 3: Lie down and put a pillow under your left shoulder. Raise your left arm above your head and with your right hand examine your left breast using the examination technique. Then lift up on your nipple and squeeze it to check for discharge. Repeat the exam on your right breast using your left hand. Notice while lying flat you can more easily identify the parts of the normal breast.



## SESSION 3—BREAST CANCER SCREENING

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### **Discuss establishing a habit**

BSE is best done once a month. Remember you are comparing your breasts from month to month. Ask yourself, does this breast feel any different than last month. Finding a change may be frightening but 80% of all changes found by women are not cancer. Try not to examine your breasts everyday or weekly. Since you are looking for a change, too frequent exams may keep you from noticing an area that is changing.

If you still have menstrual periods: Do your BSE on the last day of your period. A good way to remember is to leave a BSE note with your sanitary supplies and when you use your last pad or tampon that is the best time to do BSE.

If you do not have menstrual periods: Do your BSE on the same day every month. Choose your birthday or the day of the month you always pay bills. Tuck a BSE note in your bill paying drawer.

**Contact Your Health-Care Provider** - If you notice a change in your breast such as:

- a new lump
- nipple discharge
- a reddened area on the skin that does not go away
- dimpling or puckering of the skin
- a sore or growth
- pain that does not go away

### **Overcoming Barriers to Screening (20 min)**

- Ask participants to pair up into small groups
- Pass out screening scenarios for discussion
- Ask participants to read scenarios and discuss possible solutions with their partner
- Ask each small group to share their scenario with the group and offer their solution

### **Scenarios**

A friend you haven't seen since your school is visiting you for the day. During lunch she confides to you that she thinks she has a lump in her breast. She is afraid to go make an appointment with her health care provider. What would you say to her?

A friend you haven't seen since your school is visiting you for the day. During lunch she confides to you that she has never had a mammogram and doesn't intend to. "I've heard they are so painful," she states. What would you say to her?

A friend you haven't seen since your school is visiting you for the day. During lunch she confides she has read that women her age should have mammograms and breast examinations. She is very reluctant to participate in screening and says "I would be so embarrassed if anyone touched my breasts." What would you say to her?

## SESSION 3—BREAST CANCER SCREENING

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A friend you haven't seen since your school is visiting you for the day. During lunch she confides to you that her sister found a lump in her breast when bathing in the shower. She further adds that she herself does not examine her own breast. She says, "it's a waste of time for me to check my breasts. It all feels the same and besides that's the doctor's job." What would you say to her?

A friend you haven't seen since your school is visiting you for the day. During lunch she confides to you that her neighbor is foolish because she has annual mammograms. She continues to say "that neighbor will probably get cancer because of all that radiation." What would you say to her?

A friend you haven't seen since your school is visiting you for the day. During lunch she confides to you that her cousin was in a car accident, her breast hit the steering wheel and she ended up having breast cancer. She warns you to be careful not to bruise or pinch your breast as it may cause breast cancer. What would you say to her?

**Supplement the groups suggestions with key points from the barrier handout**

### **End session (5 min)**

- reinforce group suggestions with positive feedback
- explain that our discussion with our friends is not over. We will continue to help them as we explore the next 2 sessions - stress and social support
- further explain that this is where their contribution is most critical - we need them to help us develop realistic coping strategies that will continue to motivate these friends to take the necessary steps to protect their breast health.
- pass out BSE and mammography handouts
- review date next session
- pass out evaluations
- validate parking
- review date and topic of next session
- explain: in this session we have identified the stress areas and developed good suggestions on how that stress could be managed. We have discovered that women like yourself can be some of the best sources of information for many life issues like managing stress. In our next and last session, we will continue to explore how we can problem-solve and gain support. We will discuss how these friends can build a support network that will help them become partners in their own breast health.
- validate parking
- pass out evaluations

- **SESSION 4**

# **SOCIAL SUPPORT**

## **Begin session**

### **Attendance and Recordkeeping (5 min):**

- fill out attendance form
- questions or concerns from last session (Did anyone try any of the stress management techniques or think of others?)
- introduce social support topic - explain that in our last session we discussed what stress management techniques would be helpful for our friends. In this session we will discuss how these friends can build a support network that will help them become partners in their own breast health.

### **Introductory activity (10 min):**

- Research says that women are relational beings. During our socialization we learn to value relationships and are very gifted at cultivating friendships and see little stigma attached to admitting a lack of power or feelings of helplessness. Women are less guarded and less concerned with hiding their weakness. As women grow older, they continue to have strong relationships with other women, particularly the later years of the life cycle when male companionship is scarce. Women therefore show flexibility in being able to change their social network. Women's friendships are an example of a natural social support system.
- Pass out flowers with tags on them
- Explain that the vase is the person who can stand alone and is structurally sound
- Ask the woman who has the flower with the tag "advice" on it to put it in the vase
- explain that friends give advice and this is an example of support (what are ways to give advice that make it helpful to those that are receiving it?)
- Continue the exercise with each woman adding a flower to the vase and the facilitator announcing each kind of support until all flowers have been placed in the vase (flowers with tags will include: advice, help in crisis, encouragement, shares emotions, confronts me with truth, makes me feel normal, makes me feel special, gives me more time to do things, shares common interests, gives feedback)

## SESSION 4—SOCIAL SUPPORT

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- Explain that now as the vase is filled with flowers the vase benefits from holding on to all these flowers, therefore the vase becomes more beautiful and complete
- Explain that the bouquet is like a social network where friends are giving something to you which makes your life more beautiful and complete. The friends of life help us to achieve our goals and give us support.
- Now take away one or two of the flowers from the vase
- explain that every support system may not have all these flowers but a few flowers can still be beautiful.
- Stress the point that a quality support system, not just quantity is of equal importance.
- Take away all but one flower from the vase.
- Explain that last week as you talked to your friend about her stress you were a one-flower support system. Now, let's look at how we can fill up your friend's vase by building a quality support system.

**Instruct the participants about social support facts (15 min):** research suggests that women are usually great support givers. For example, as a group we have demonstrated the 5 rules for giving support and they are:

- listen - be a good listener
- give feedback - let the person know what you have just heard
- non-judgmental attitude - be sympathetic to their concerns
- appropriate suggestions - offer helpful advice
- keep in touch - show you care by inquiring about their progress

**Explain:** research also suggests that women are not always good support receivers. Many women have a vase of wilted flowers or a weak support system because they have a hard time asking for support when they need it most. Women have a fear of bothering other people, which can result in a system that is:

- unpredictable - having expectations that a loved one will know automatically what we need.
- counterproductive - some friends may sabotage efforts to improve oneself which results in dependency instead of fostering independence. We need to learn how to keep people who are not helpful from getting in the way and taking the risk of asking people who could be helpful for their support.
- time consuming - it takes energy to maintain a system, let go of people who are not relevant.

Before we look closely at the support system our 3 friends have, let's discuss what a support system is, what makes it effective, and where we find available sources.

## SESSION 4—SOCIAL SUPPORT

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### **Purpose of a Support System:**

A support system helps the individual to cope with the stress that comes from their environment or with life's transitions. They help an individual make contributions and reach their personal goals.

### **Definition of an Effective Social Support System:**

- a resource pool: includes people, things, environment and beliefs
- identifying goals and moving in the right direction: distinguish my goals from other people's goals and organizations.
- increases my strength: a good supportive network should enable me to grow as a person and provide assistance during times of stress.

### **Types of Social Support**

Caring support: someone who makes us feel loved, shows us concern and understanding.  
Example - a friend, family member or spouse.

Physical support: something that provides material help like money, food, clothing or shelter.

Example - having a savings account, working at a job, owning a house.

Information support: experiencing support by being with people who share advice and give suggestions.

Example - this group session or clubs, experts in solving particular kinds of problems, role models.

Approval Support: experiencing support by being with people who value what you do and offers positive feedback which increases your self-esteem.

Example - working as a volunteer or a job supervisor, health care provider after you agree to participate in screening.

***show visual aide #1 (Mind Map with 4 lines and one line expanded upon) (Handout #9)***

### **Begin Mind Map Activity (30 min):**

- instruct participants to pair up in same groups as last session
- pass out scenarios with expanded stories (giving each group their same scenario as last session)
- read again the 3 friend scenarios to familiarize the group with our 3 friends
- explain that with this activity we will evaluate each friend's support system
- pass out maps and explain that mind mapping is a strategy for organizing thoughts

## SESSION 4—SOCIAL SUPPORT

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- encourage participants to draw added lines from each of the 4 lines that represent the four types of social support categories. Explain these lines should be labeled with people or things that we assume are part of our friend's life and that fit these categories.
- on the completion of their map, ask them to evaluate areas where their friend lacks support.

"Friends in need stories":

### **Friend A**

A friend you haven't seen since school has just finished catching you up on her life. She has recently received a raise in her job which is well-deserved since she works a 60 hour week. She lives for her work and has very few outside interests. Last week you convinced her to see her doctor regarding the breast lump she found while bathing in the shower. Her doctor has recommended that she have a biopsy of the lump. She reports that she is planning on having the surgery when she can fit it into her schedule. "Right now I'm under important deadlines at work and there is no one to take on the responsibility but me," she says. "Besides what if it's cancer-all that surgery and chemo. What if I can't keep up with my new job?" she adds. "I can't possibly think about it right now," she says.

**Additional conversation:** You call to find out if friend A has scheduled her biopsy appointment yet. She reports that now is not a good time to have surgery as she has recently purchased a condominium and is having it re-decorated. "It's hectic right now, with all these decorating decisions to make and an important presentation to develop for work." The secretary has been asking me the same thing," she says. "In fact, I am so furious with her because she continues to tell me about some Aunt of hers that died of breast cancer. I wish she would keep her horror stories to herself," she adds.

### **Friend B**

A friend you haven't seen since school has just finished catching you up on her life. She spends most of her time during the week caring for her grandchildren while her daughter works. She feels so tired at the end of the day but is determined to actively accompany her husband with his retirement agenda. Her husband is an avid fisherman and likes to travel in their motorhome on weekends. She rarely thinks about her own health and can't remember the last time she has had a mammogram. "My family has always come first even if it means my needs come last," she says. "I worry all this commotion in my life will affect my health but what choice do I have? I don't have the time to have a breast check-up anyway," she admits.

**Additional conversation:** You see friend B in the grocery store and she introduces you to her 2 granddaughters. It is obvious that these 2 granddaughters are the love her life. "I'm picking up a few things so the girls and I can make cookies," the friend says. "My mom said we can stay overnight with Grandma while she goes on her trip," says one of the granddaughters. "We're so lucky, we get to stay with Grandma a lot," adds the other child. Friend B confides that her daughter has an active social life besides working her job so many times the girls stay overnight with her. "My husband reminds me that we're supposed

## SESSION 4—SOCIAL SUPPORT

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to be retired so I shouldn't work so hard. He worries that the grandchildren are too much work for me," she says. "I can't bring myself to tell my daughter no," she adds.

### **Friend C**

A friend you haven't seen since school has just finished catching you up on her life. She is married, has a part-time job and spends a lot of her time in volunteer activities. Her doctor reported to her that her mammogram showed changes in her breast and that she needs another mammogram in 6 months. "I must admit I worry about having breast cancer almost every day ever since I had that mammogram. I've been short-tempered with my husband and children a lot lately," she says. "I'm so confused as to what this all means and my husband tries to help but he can't possibly know what it would be like to lose a breast," she adds.

**Additional conversation:** You call to find out if your friend has found out anymore information on what her mammogram results mean. She tells you she hasn't had time to call the doctor's office and besides she doesn't know what questions to ask. "My husband tells me to stop worrying about having breast cancer as he thinks the doctor would have said if it was serious," she says. "But I don't know if it's serious and if it is, why isn't someone doing something about it," she adds.

**Ask each small group to identify what sources of support each friend has and where they are lacking support.**

(Probe: friend A may have physical, information and approval support but is lacking caring support. Does it appear that she has friends and family who make her feel cared for? Although it appears the secretary wants to be supportive, her horror stories are counterproductive. Friend A reacts by not taking any action at all .)

(Probe: friend B may have physical and caring support but is lacking information and approval support. Is she around women her own age for sharing information and advice? Is she getting approval support for caring for her grandchildren? Although it appears she has plenty of caring support, this type of support may be taking energy away from taking care of her health.)

(Probe: friend C may have some caring, physical and information support but is lacking approval support. Is she getting reinforcing messages and advice from her health care provider? Although her husband is someone who is nurturant support, she may have the expectation that he will automatically know what she needs.)

**Ask the group if they know of people in their life like our 3 friends.**

**Discuss - S.O.S or SEEKING OUT SUPPORT (30 min) (Handout #10)**

### **S.O.S rules for getting support:**

- identify the type of support you want and from whom
- state problems clearly to this person
- ask the person if they can help

## SESSION 4—SOCIAL SUPPORT

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- imagine yourself in this person's situation - how would you feel
- re-evaluate what support you expect based on their help
- ask for the support that you want
- express appreciation - let them know how the support has helped you
- be sensitive to excessive demands

*Pass out the goal setting handouts.*

### **Setting Goals for Eliciting Support - explain the steps in the goal process (Handout #11)**

**Step 1:** gather information - we have identified the areas where our friends need support

**Probe:** friend A needs caring support (help from her secretary and you)

friend B needs information support and appropriate caring support (daughter and husband, seeking out a hobby that involves other women)

friend C needs approval support and appropriate caring support (health care provider and husband)

**Step 2:** select one goal to achieve - realistic vs unrealistic

- keep them short term
- nonoverwhelming
- easy to reach to minimize failure

**Ask the group what would be realistic goals for our 3 friends.**

**Probe:** friend A's short term realistic goal may be her desire to ask her co-worker for the kind support she needs. An example of an unrealistic goal is to expect the secretary to know what kind of advice or help she needs to schedule the appointment.

Friend B's short term realistic goal may be to communicate to her daughter that it is important for her to take care of her health by having regular mammograms. An example of an unrealistic goal is to stop caring for her grandchildren in order to have time for herself.

Friend C's short term realistic goal may be that her spouse will understand her feelings about breast cancer. An example of an unrealistic goal is wanting her spouse to understand every feeling she has.

In addition, another realistic goal for friend C may be a desire for more information from her health care provider. An example of an unrealistic goal is to expect answers to questions that have not been asked.

**Step 3:** identify factors that interfere with success

- fear of bothering people
- having unrealistic expectations



## SESSION 4—SOCIAL SUPPORT

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- selecting the appropriate people who will not sabotage our efforts

**Ask the group what factors may interfere with our 3 friends success.**

**Probe:** friend A may think the secretary is interfering in her personal life. The secretary's job is to schedule the biopsy on

Friend's A work calendar and is showing her frustration with friends A's reluctance.

Additionally, the secretary may be telling her the stories to motivate her to action but the result is that it is sabotaging her efforts to schedule the biopsy.

Friend B may be afraid to talk to her daughter about her needs because she does not want to bother her or fears she will not see her grandchildren.

Friend C may have unrealistic expectations as she thinks her spouse should understand how she feels and that her health care provider should know that she is confused over her mammogram results.

**Step 4:** outline a plan -- generate a "to do list" of how to take action to accomplish goal

**Ask the group what action our 3 friends should take.**

**Probe:** friend A would tell the secretary that hearing the horror stories regarding women with breast cancer is not helpful. She should suggest to sit down, discuss the work calendar and identify areas where meetings or appointments could be rescheduled to make time for the biopsy.

Friend B would call the mammography facility for a lunch time appointment. Suggest that her daughter would meet her mother at the mammography facility. While friend B is having her mammogram, her daughter could take the children to lunch at a fast-food place.

Friend C would set aside some quiet time with her husband to discuss her feelings about breast cancer. She asks that he give her support by listening, being sympathetic and help her develop her thoughts into a question sheet. She then calls her health care provider's office and asks if the provider could call her when available to answer her questions.

**Step 5:** review your goal -- is my goal realistic, did the action work and if not, why not

**Ask the group to imagine what was the outcome for our 3 friends.**

**Probe:** friend A had a realistic goal but her action did not work because she continued to have excuses for why she scheduled could not be changed. Since she did not schedule the biopsy, her secretary did not stop talking about her horror stories.

Friend B had a realistic goal and the action she took worked.

Friend C had a realistic goal and the action she took worked in part. Her husband helped her talk through her concerns so she was able to create a question sheet. Her health care

## SESSION 4—SOCIAL SUPPORT

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provider talked with her about her questions but she still felt she needed more information. Her health care provider suggested that she call the Cancer Information Service at 1-800-4-cancer or read some specific books.

**Step 6:** measure your goal -- evaluate the success of your action plan.

**Ask the group if the 3 friends were successful.**

**Probe:** friend A may not be able to ask for the type of support she needs. As her friend, it may be up to you to point out to her that the secretary is worried and is trying to motivate her to action. By not scheduling her appointment results in the secretary becoming more anxious. Suggest to her a compromise between her and the secretary. The compromise would be that she follows through on the biopsy and the secretary does not mention any stories. Offer to accompany the friend to the biopsy.

Friend B asked her daughter for help so she could complete a mammogram. Her daughter was unaware of how important screening was to her mother.

Friend C was able to ask for the type of support she needed from her husband that helped her become more assertive with her health care provider. Although some of the explanations seemed confusing, she is now aware of other resources that could provide more information.

### **Formation of Peer-led Group (10 min): (Handout #12)**

In this session, we have helped our 3 friends build a valuable support system. As participants in this research study, you have built a support system that has helped you acquire more information and develop new skills. It is our hope that you can continue to share informational and approval support by continuing to meet as a group. Although, I will no longer be a part of your group, let's talk about how this group could continue to meet.

*Pass out peer-led handouts.*

Discuss handout by reviewing the content with the group.

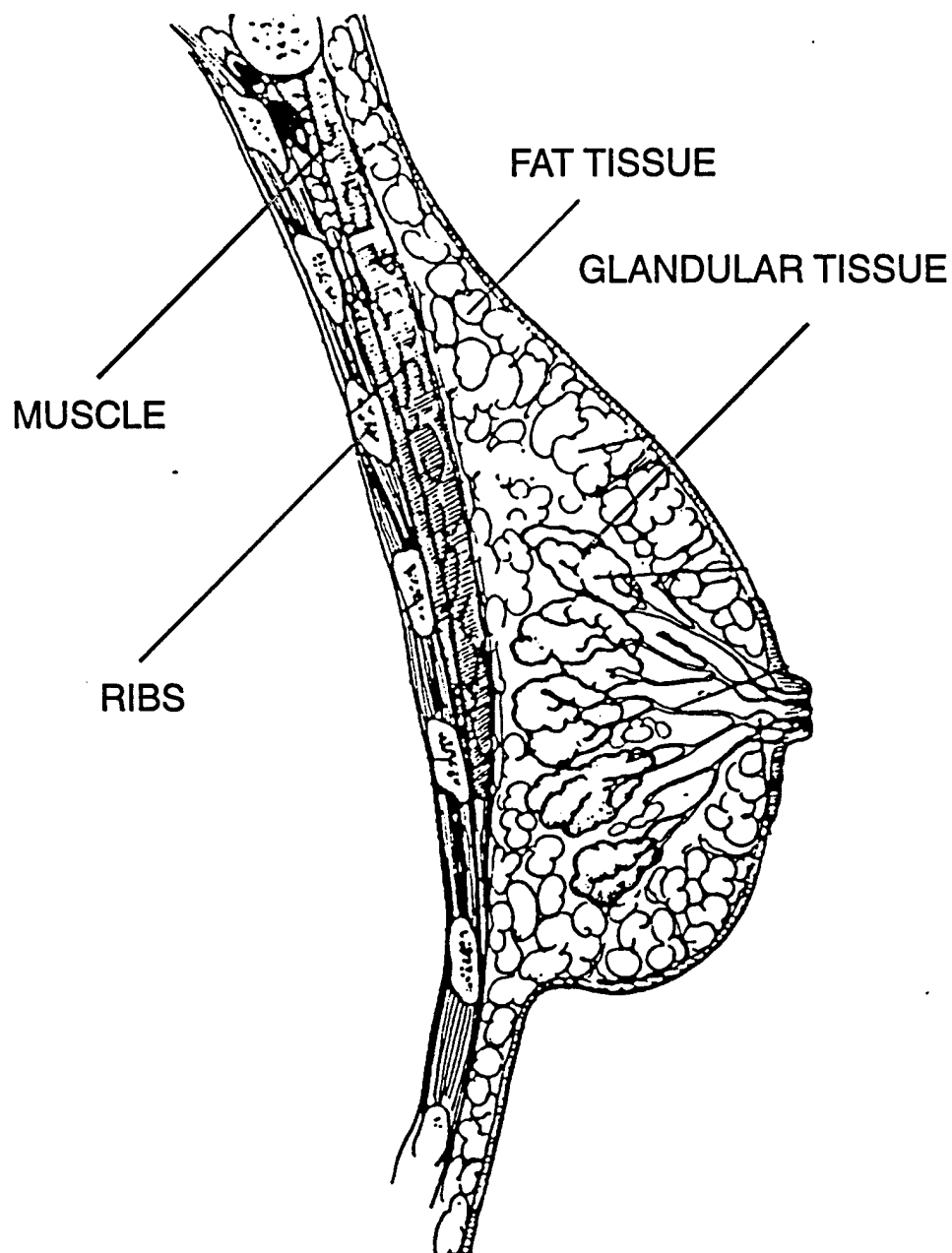
### **Pass Out Friends for Life information**

#### **End session (5 min)**

- express participation for their attendance and participation
- answer any questions
- pass out certificate of study participation

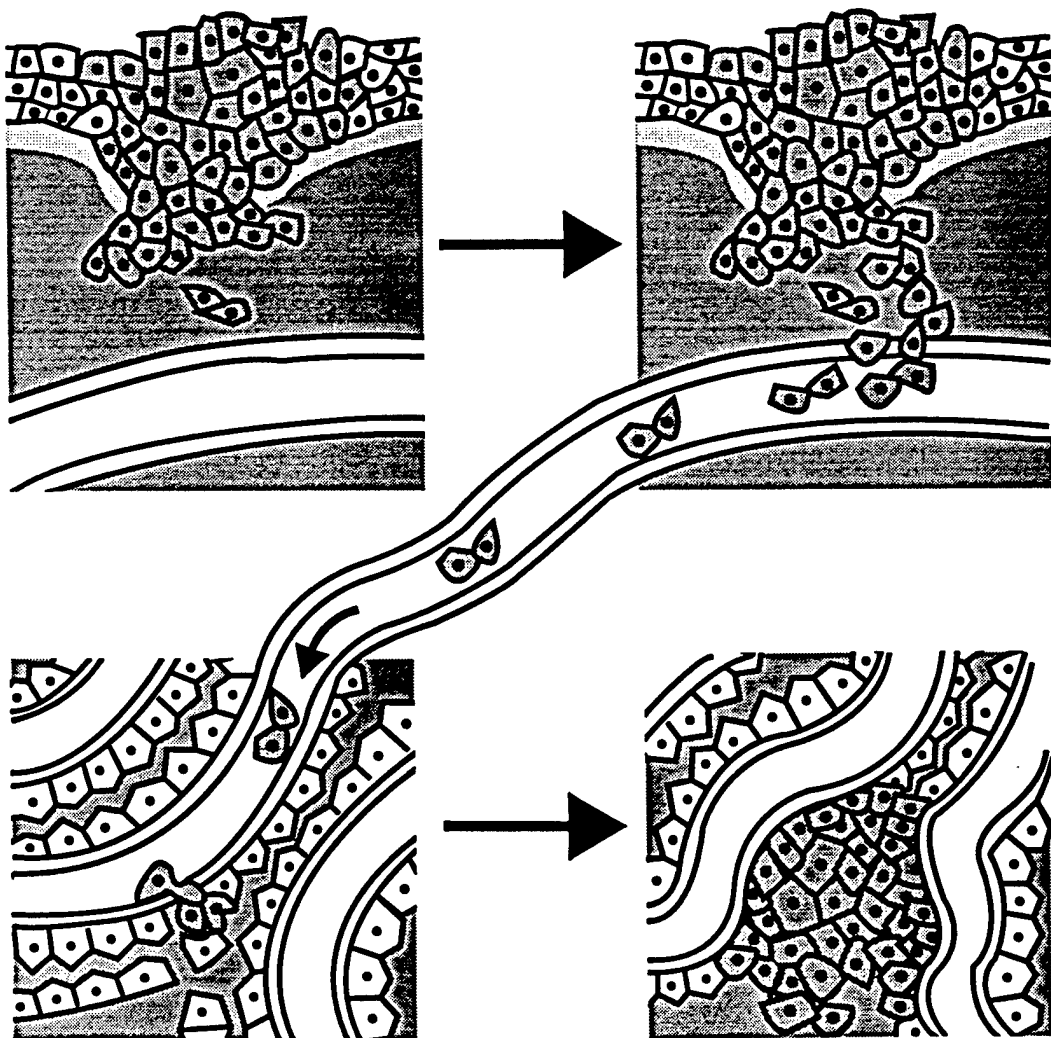
## Group Session Posters

# ▶ ANATOMY OF THE BREAST





# HOW CANCER CELLS METASTASIZE



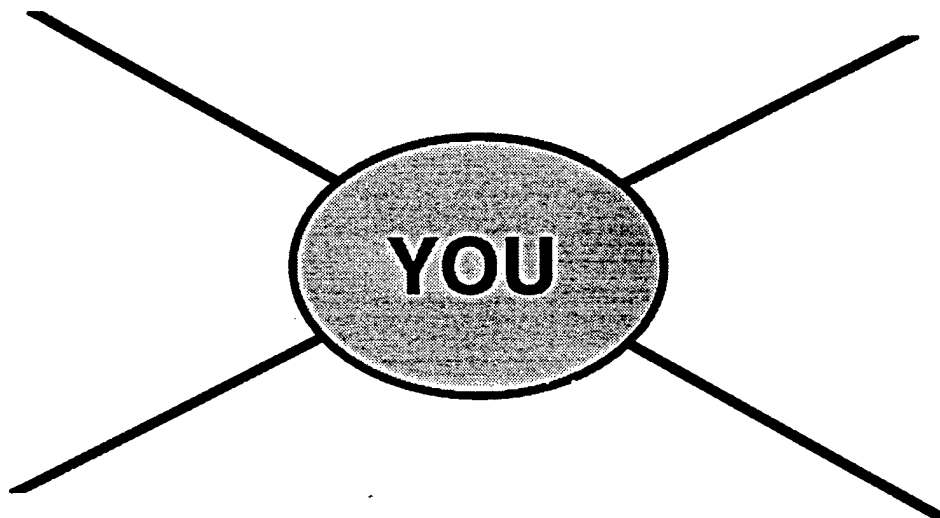
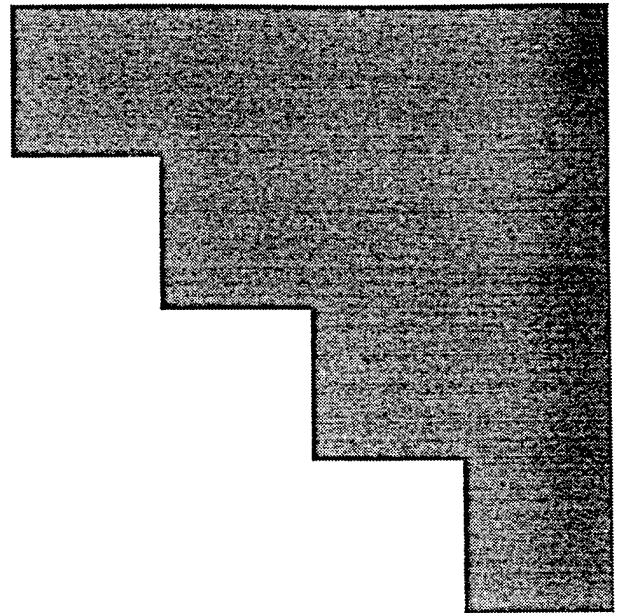


## **S.O.S. RULES FOR GETTING SUPPORT**

- identify the type of support
- state problems
- ask for help
- imagine yourself in this person's situation
- re-evaluate the support needed
- ask for the support
- express appreciation
- be sensitive

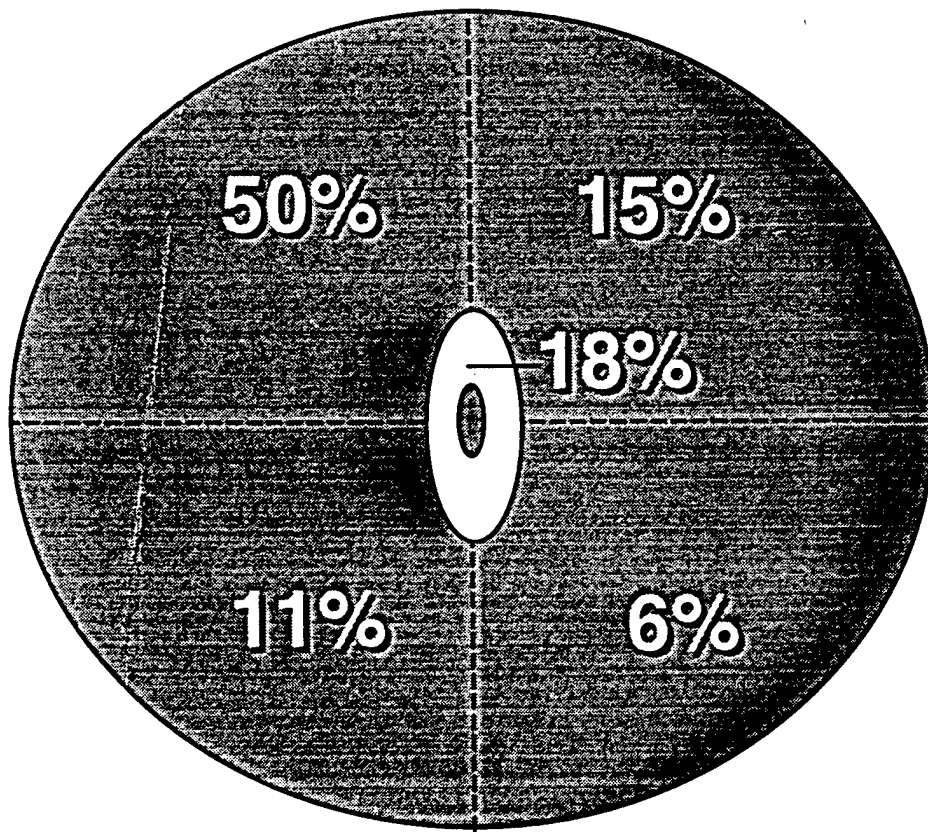
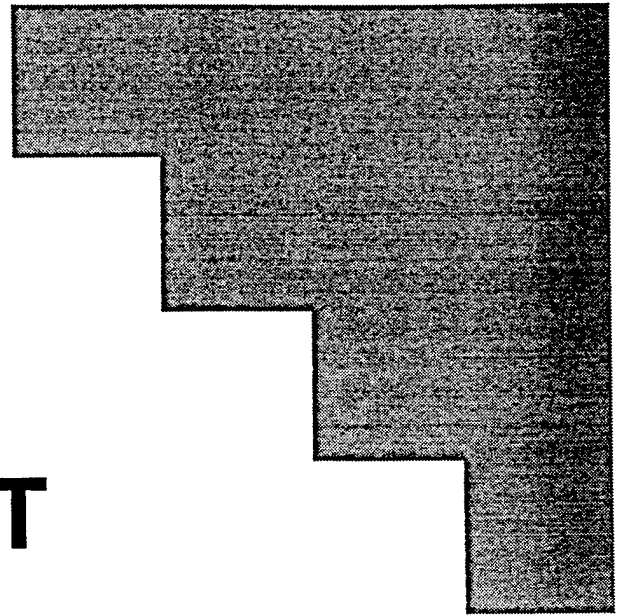


# MIND MAP



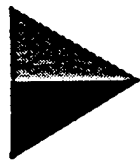


# LOCATION OF BREAST CANCER

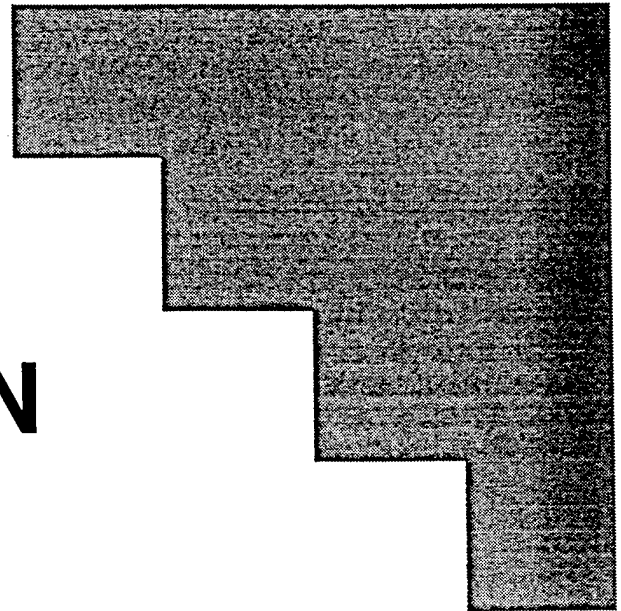


Right  
Breast





# **DETECTION METHODS**



## **Mammography**

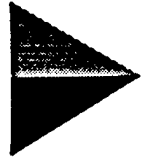
- detects earliest stage before it can be felt
- allows more treatment options
- best screening test

## **Clinical Exam**

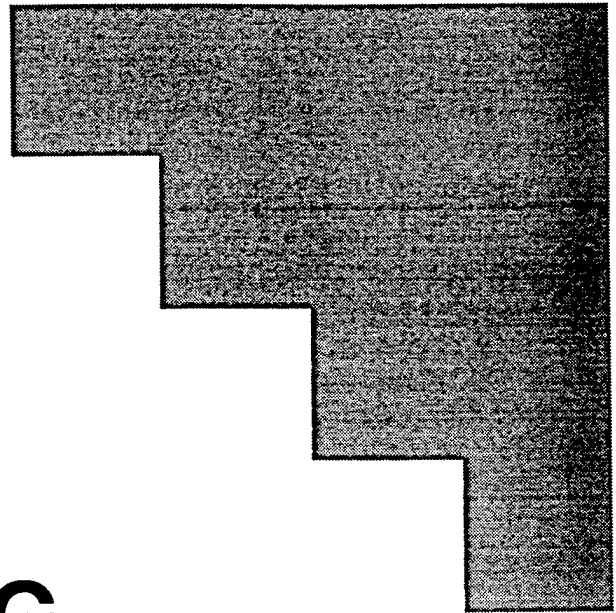
- can be done with pap or physical
- may detect 8-10% of cancers missed

## **BSE**

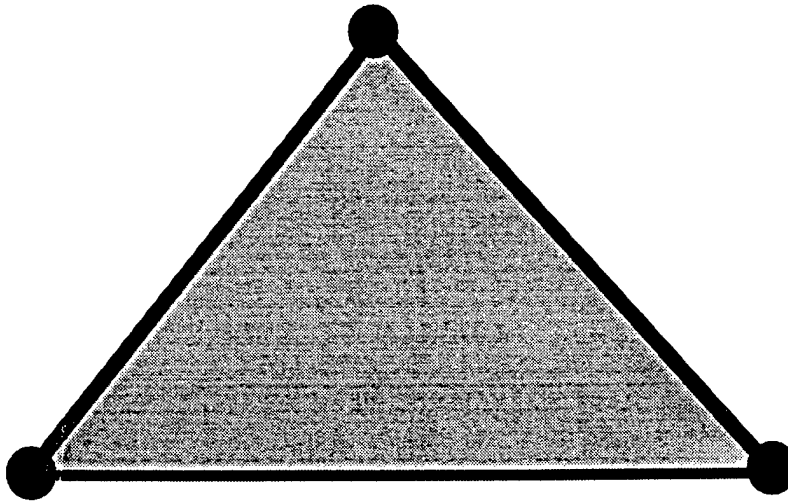
- no cost, convenient
- gives woman control over and knowledge of body



# BREAST CANCER SCREENING PROGRAM

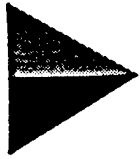


Mammography



Clinical Breast  
Examination

Breast  
Self-Examination

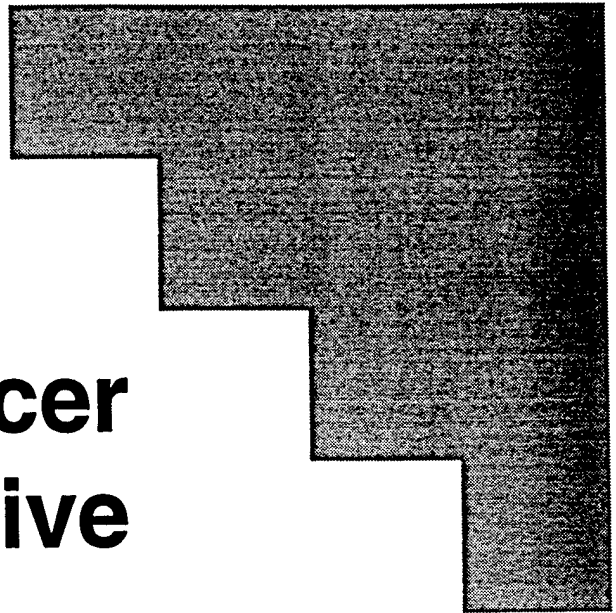


## **RISK FACTORS**

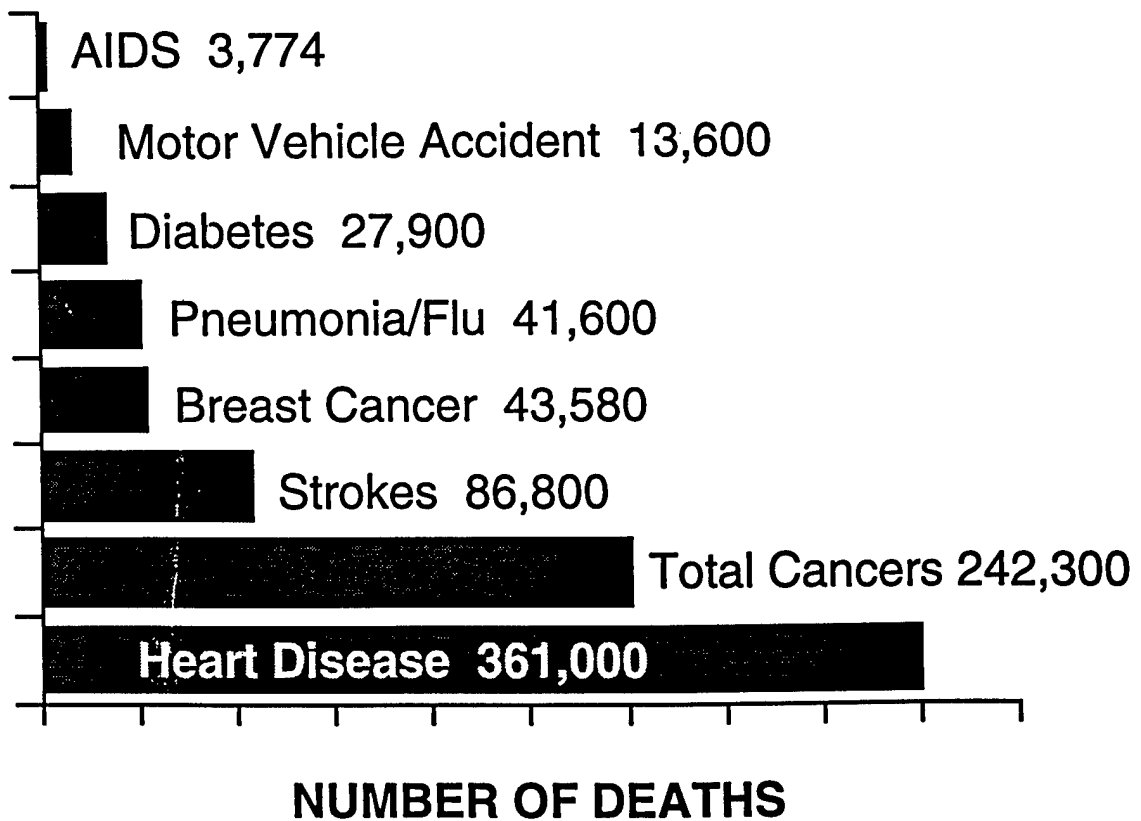
- age
- family history
- starting menstruation before age 12
- having first child after age 30
- never having children
- starting menopause after age 55
- atypical hyperplasia found on biopsy
- past history of breast cancer



# Breast Cancer in Perspective



Selected Causes of Death in  
1991 for Women



## Group Session Handouts



• BREAST CANCER AWARENESS

# BREAST CANCER FACTS

## Breast Cancer

### *What we know:*

- 90% of women will never develop this disease
- 3 out of 4 women who get breast cancer do not die from the disease
- 20% of breast cancers occur in women under 50 - most common late 60's and older
- early detection can save your life - by practicing methods of early detection you have some control over surviving

### Reasons for increase in breast cancer cases:

- women are living longer - more likely to survive to the ages when women get breast cancer
- mammography has improved our ability to detect cancer at early stages - finding more cancers sooner

Researchers do not have all the reasons to explain the increase in cases - changes in diet, exercise, delays in childbearing, earlier age of menstruation and possible exposures to environmental pollutants may play a role and are currently being studied. To date, nothing has been proven to prevent breast cancer.

## Risk Factors:

- age
- family history
- starting menstrual periods before age 12
- having your first child after age 30
- never having a child
- beginning menopause after age 55
- atypical hyperplasia - a non-cancerous breast abnormality found by breast biopsy
- past history of breast cancer

## Potential Risk Factors -

### *inconclusive at this time*

- hormone replacement
- alcohol
- overweight
- diet
- oral contraceptives



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# LIFE QUALITIES

**A**ll of the Life Qualities listed below are considered meaningful by most people. But, which one are the most important for you? Check the five that you consider the most significant to you right now in your life (personal and work-related).

- |   |   |
|---|---|
| <input type="checkbox"/> Accomplishment | <input type="checkbox"/> Adventure          |
| <input type="checkbox"/> Affection      | <input type="checkbox"/> Authenticity       |
| <input type="checkbox"/> Autonomy       | <input type="checkbox"/> Camaraderie        |
| <input type="checkbox"/> Challenge      | <input type="checkbox"/> Creativity         |
| <input type="checkbox"/> Expertise      | <input type="checkbox"/> Financial Security |
| <input type="checkbox"/> Happiness      | <input type="checkbox"/> Health             |
| <input type="checkbox"/> Honesty        | <input type="checkbox"/> Inner-Peace        |
| <input type="checkbox"/> Integrity      | <input type="checkbox"/> Involvement        |
| <input type="checkbox"/> Leadership     | <input type="checkbox"/> Relaxation         |
| <input type="checkbox"/> Responsibility | <input type="checkbox"/> Self-Development   |
| <input type="checkbox"/> Self-Respect   | <input type="checkbox"/> Spirituality       |



- BREAST CANCER AWARENESS

# IMPROVING YOUR COPING SKILLS

## *Simple Steps for Reducing Stress*

**Y**ou can reduce stress and enjoy life more by using this worksheet to identify the skills you'd like to develop. Then practice until good coping skills are your everyday habits.

### Stress Management

*People who feel in control of their lives are able to manage their stresses.*

- I feel in control of these parts of my life: \_\_\_\_\_  
\_\_\_\_\_
- Two people I know who seem in control of their lives are: \_\_\_\_\_
- Four things they do which I can try: \_\_\_\_\_  
\_\_\_\_\_
- Other things I could do to gain control over my own life: \_\_\_\_\_  
\_\_\_\_\_

### Commitment

*When you are committed to your own life, stresses are easier to take.*

- I am committed to and enjoy these parts of my life: \_\_\_\_\_  
\_\_\_\_\_

- Two people I know who seem to enjoy their lives are: \_\_\_\_\_
- Four things they do which I could try: \_\_\_\_\_  
\_\_\_\_\_
- Other things I could do to help make my life more meaningful: \_\_\_\_\_  
\_\_\_\_\_

### Risk

*When you are willing to take risks, life becomes more satisfying. Risks include everything from traveling overseas to getting married.*

- Three things I'd like to try: \_\_\_\_\_  
\_\_\_\_\_
- Things which would help me try them: \_\_\_\_\_
- I agree to try these two new things this month: \_\_\_\_\_
- I agree to try these two new things this year: \_\_\_\_\_

### Specific Skills

Use this list to help identify and develop your coping skills. Check those skills you practice regularly. Each month check one to two skills you'll improve.

#### Physical skills

- ☐ eat 3 meals daily
- ☐ exercise at least 3 times weekly
- ☐ don't smoke
- ☐ drink alcohol no more than 3 times per week

#### People skills

- ☐ ask for help when I need it
- ☐ say how I feel
- ☐ give and receive love
- ☐ say "no" if I need to

#### Personal management skills

- ☐ plan my time well
- ☐ on time when I'm expected
- ☐ take "time out" to get perspective
- ☐ know how to laugh at life

#### Action skills

- ☐ have hobbies
- ☐ feel good about what I do
- ☐ people can count on me
- ☐ try new things





• BREAST CANCER AWARENESS

# STRESS MANAGEMENT

**M**ajor work and life changes are common. Whether these changes are welcome or unwelcome, all can be extremely stressful unless we learn to adjust to them. Taking time to recover, refocus and regenerate following life changes can help us survive and even thrive.

**Recover** - regain your sense of balance by stepping back from the situation

- plan a weekend getaway
- go to a movie
- exercise
- share your feelings

**Refocus** - take a good look

- take time to review what has just happened
- think about why it happened and what it might mean
- sort out your feelings by talking to trusted people

**Regenerate** - all change is stressful

- get extra rest
- avoid alcohol
- increase your circle of support
- eat properly

## Stress Management Tools:

- *relaxation exercises* - deep breathing and simple stretches can relieve tension
- *exercise* - 20 minutes of walking, cycling or swimming can best meet your body's needs in times of stress
- *laughter* - research has shown that laughter increases relaxation
- *meditation* - an ancient technique in many Eastern traditions for coping with daily stress
- *visualization* - 2 or 3 minutes of guided daydreaming can help you to relax



• BREAST CANCER AWARENESS

# ABCs OF STRESS RELIEVERS

**A**sk for help

**B**e forgiving

**C**all up an old friend

**D**aydream

**E**at a good breakfast

**F**ly a kite

**G**o for a brisk walk

**H**ug someone you love

**I**nitiate a conversation

**J**oin a book club

**K**iss a baby

**L**augh out loud

**M**ake a list

**N**egotiate a solution

**O**rders take-out food

**P**aint a peaceful scene  
in your mind

**Q**uit complaining

**R**ead something funny  
every day

**S**mell a rose

**T**ake a long bath

**U**se your imagination

**V**oice your opinion

**W**atch a really good movie

**X**erox a sentimental photograph

**Y**awn and stretch

**Z**ip down the street



- BREAST CANCER AWARENESS

# BREAST CANCER SCREENING PROGRAM

**T**hese screening tests for breast cancer are generally accepted methods for detecting breast cancer at it's earliest stage. At this time we cannot prevent breast cancer but we do know that if the cancer is detected early women can survive from this disease and lead normal lives.

- mammography (x-ray of the breast)
- clinical breast exam (exam by physician or nurse practitioner)
- breast self-examination (BSE)

## Advantages of Early Detection Methods

| Mammography  | Clinical Breast Exam   | Breast Self-Exam  |
|--|--|---|
| detects earliest stage before breast cancer can be felt    | can be done with pap test or physical                                    | no cost, convenient   |
| allows more treatment options                              | may detect 8-10% of cancers missed by mammography                        | gives women control over their breast health care                         |
| ACS recommends women over 50 have a mammograms every year. | ACS recommends women over 50 have an exam by their provider once a year. | ACS recommends women start examining their breasts at age 20 every month. |

## Screening Reduces Mortality

- early detection results in a 90% survival rate
- programs using mammography and physical examination every 1 to 3 years reduces breast cancer deaths among women ages 50-70 by approximately 40%
- women over 50 are the most likely to benefit from early detection of breast cancer but are the least likely to have the necessary test
- a recent WA state survey showed that 80% of the women in this state 40 and older have had a mammogram



• BREAST CANCER AWARENESS

# REASONS WOMEN GIVE FOR NOT HAVING MAMMOGRAMS

**Discomfort/Pain:** Some women say that having a mammogram is uncomfortable for just a few moments. That is because the breast is not in a natural position during a mammogram. The breast is compressed to an even thickness. This compression helps get a good picture of your breast and lowers the amount of radiation needed. Although it may be a bit uncomfortable, the compression only lasts about 30 seconds. A mammogram is the best test for finding early breast cancer.

**Embarrassment:** The mammography procedure is done by a woman who is sensitive to your privacy needs. You will be given a gown and told to undress only from the waist up. The machine is in a private room with one door that is kept closed at all times. Many women feel the same way you do so every effort is made to make you feel comfortable.

**Anxiety/Fear of Procedure:** The mammography technician will take you into a special private room for your mammogram. Then she will ask you to take everything off from the waist up and put on a hospital gown that opens in front. At first, you will stand next to the

mammography machine and the technician will place your breast between two plastic plates, which will be pressed together to flatten your breast as much as possible. Although this may be a little uncomfortable, the squeeze only lasts for about 30 seconds. A total of 4 pictures will be taken, 2 of each breast, one from the top and one from the side. Your mammogram results will be sent to your doctor, who will let you know the results.

**Inconvenience:** The mammogram itself usually only takes about 30 minutes from the time you walk into the facility until the time you walk out. Most of us these days lead very busy lives so many facilities offer early morning and evening appointments.

**Radiation:** The radiation dose from current mammography technique is extremely low and averages 0.1-0.8 rads dose per exposure. This is 100 times less than the dose used in 1976. Most mammography facilities have accreditation from the American College of Radiology and the FDA which requires facilities to have trained and experienced staff as well as modern mammography equipment.

**Cost:** The average cost of mammography is between \$90 and \$150 which includes all technical and professional fees. Medicare pays 80% for a screening mammogram every 2 years. Washington state mandates that third party insurance carriers reimburse for screening mammography.

**Fear of Finding Cancer:** Maybe you would rather not know if you have breast cancer. Maybe you prefer not to deal with the hassle that may come with breast cancer treatment. Some women feel that as long as they feel fine, they don't want to look for trouble. However, other women say something else, which is very true: If you have cancer, you'll find out eventually, so why not know now, when you can do more about it? Unless you have regular mammograms, you don't know your breasts are "in trouble". When breast cancer is present and is found by a mammogram, you sometimes have as much as a 1 and a half to 2 year head start on treating it. And, the sooner you do something about breast cancer, the more likely the treatment can be simpler, easier and less hassle than if you wait.

### **Injury to Breast Can Cause**

**Breast Cancer:** Science as yet does not know what causes breast cancer but there is no evidence that squeezing, bruising or any type of injury to the breast can cause breast cancer. Breast cancer can develop unnoticed for many years without any symptoms. The injury only draws attention to an existing cancerous area.

### **Lack of Perception of Risk:**

Most breast cancers occur in women aged 50 and older and as women get older, they are more likely to get breast cancer. Many women believe that they don't need mammograms because no one in their family has had breast cancer. However, over 80% of all breast cancer occurs in women without a family history of breast cancer.

### **Lack of Physician Referral:**

Don't assume because your doctor hasn't told you to have a mammogram that she or he doesn't believe it's important. Studies have found that most doctors say they recommend regular mammograms for their women patients over 50 years of age. It might have slipped your doctor's mind in the past to talk to you about it especially if you had some other medical problems. Most doctors appreciate being reminded about their patients' need for mammograms.

**Fatalistic Attitude:** Some women do feel that having a mammogram is just looking for something they have no control over anyway. However, breast cancer is one kind of trouble you do want to look for while it is still early.

Mammograms can help you have some control over your health. If there are people in your life who depend on you, it is even more important to find out early if you have a disease. Breast cancer is the most common disease of women but it is also curable when found early through mammography.



• BREAST CANCER AWARENESS  
**MINDMAPPING**



## • BREAST CANCER AWARENESS

# SUPPORT SYSTEMS

**A** support system helps individuals to cope with the stress that comes from the environment or with life's transitions. They help an individual make contributions and reach their personal goals.

### Sources of Support:

- *close friends/family*: people who provide caring support
- *role models*: people who show us what is possible and are a source of valuable information about opportunities and problems associated with a given role.
- *people with common Interests*: people who share common interest or concerns which results in keeping individuals motivated.
- *helpers*: people who can be depended on in a crisis such as experts in solving particular kinds of problems.
- *people who respect competence*: people who respect the skills one has already developed and who value our contributions.
- *referral agents*: people who connect one with resources in their environment through their knowledge and through organizations.
- *challengers*: people who can motivate one to explore new ways of doing things and may not be personal friends.

## S.O.S or SEEKING OUT SUPPORT

### S.O.S rules for getting support:

- identify the type of support you want and from whom
- state problems clearly to this person
- ask the person if they can help
- imagine yourself in this person's situation - how would you feel
- re-evaluate what support you expect based on their help
- ask for the support that you want
- express appreciation - let them know how the support has helped you

- be sensitive to excessive demands

### S.O.S. rules for giving support:

- listen - be a good listener
- give feedback - let the person know what you have just heard
- non-judgmental attitude - be sympathetic to their concerns
- appropriate suggestions - offer helpful advice
- keep in touch - show you care by inquiring about their progress



- BREAST CANCER AWARENESS

# SOCIAL SUPPORT

## *Setting Goals Worksheet*

1. Where do I need support in my life?

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2. What short term goal would I like to achieve?

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3. What obstacles may interfere with my success in achieving this goal?

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4. What action do I need to take to achieve my goal?

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5. Does my goal and action plan seem realistic?

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6. Did my action plan work (if not, why)?

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## **PEER-LED GROUPS**

**Purpose:** to continue the social support network that has been established by participating in the research study.

**Time Interval:** meet once or twice a month

**Location:** home, church hall, restaurant, park (for walking exercise)

**Leadership:** establish a contact person or 2 contact people (to lessen the burden)

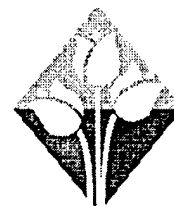
### **Questions to explore during group session:**

1. What major accomplishments or concerns do I have to share with the group?
2. What major stressors have I encountered and how did I cope with them?
3. What are my current feelings about my breast cancer risk? (diminished vs acute)
4. What further information should we seek out as a group?
5. Should social activities be combined with this group? (book club, quilting)
6. Should we develop a buddy system for physician visits?
7. Should we involve the group in breast cancer awareness activities every October?
8. Should we establish a telephone tree to inform the group of speakers or seminars in our area?

### **Suggested group activity at first peer-led session:**

- list expectations group members have of attending group
  1. what will I give to the group
  2. what will I gain from the group
  3. attendance at all meetings vs some meetings
- assign session maintain tasks
  4. develop a telephone tree
  5. research areas of interest
  6. communicate to group via reminders of meeting time and location
  7. establish location facilities
  8. seek out special events of interest (Race for the Cure)

## Consent Form



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**CONSENT FORM**

**BREAST CANCER AWARENESS: LEARNING ABOUT YOUR RISK**

**Principal Investigator:** Barbara Cochrane, PhD, RN  
Nurse Scientist  
Fred Hutchinson Cancer Research Center  
1124 Columbia Street, MP 1002  
Seattle, WA 98104  
**24-Hour Phone:** (206) 667-6814

**Introduction**

Breast cancer is the second most common major cancer occurring in women. As many as 1 in 9 women will develop breast cancer during her lifetime. Thus, it is important for women to understand their risk for breast cancer and what health and screening behaviors they can follow.

**Purpose**

The goal of this study is to evaluate and understand women's reactions to receiving an estimate of their risk for developing breast cancer and to a four-session group-counseling intervention to help them better understand and cope with that risk. The study will recruit about 350 women between the ages of 40 and 85 who are interested in learning more about their risk for developing breast cancer.

**Procedures**

Before this visit, you received a phone call from our study staff, who explained the study and sent you a packet of forms to complete. The questions on those forms asked about your possible risk factors for breast cancer, perceptions of your risk, emotions, usual ways of coping, support you receive, perceptions of quality of life, and health and screening behaviors. Using this information, an analysis of your breast cancer risk will be made, based on current scientific knowledge.

During this visit, you will be informed of this risk estimate and provided with additional information about what this means for you. A small number of these information sessions, chosen at random, will be tape-recorded to ensure the sessions are conducted consistently and that your questions are answered appropriately. You will also be invited to participate in four weekly group-counseling sessions during which you will be given further information about breast cancer risk factors, coping with risk, and strategies for following recommended breast health and screening guidelines. You will be telephoned by our staff within a week of this visit and scheduled for the group sessions of 6 to 10 women.

I have read and understand this page of the consent form:

\_\_\_\_\_  
Participant Initials/Date

\_\_\_\_\_  
Witness Initials/Date

You will receive 3 more packets of forms in the mail to fill out and return. These packets will arrive soon after this clinic visit, about 3 months after your first contact with the study, and about two years after your first contact with the study. These packets will contain questions like the ones you filled out before this visit.

### **Risks**

There are no physical risks involved in this study. Some women may experience mild emotional discomfort when answering questions about their feelings, receiving information about their risk of breast cancer, or talking about experiences and feelings in group sessions. You may refuse to answer any questions, and you may talk with the Nurse Counselor at this visit or during the group counseling sessions about any discomfort you are feeling.

You are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. Other than medical care that may be provided, you will not receive any compensation for your participation in this research study; however, you understand that this is not a waiver or release of your legal rights.

### **Time Involved**

In addition to the time you have already put into the study, your participation involves this risk feedback session (about 45 to 60 minutes), the four group-counseling sessions (about 1½ to 2 hours each, for a total of 6 to 8 hours), and completing the additional three forms packets that will be mailed to you (about 1 to 1½ hours each for a total of 3 to 4½ hours).

### **Benefits**

By taking part in the study activities, you will receive information about your estimated risk of breast cancer and how to cope with that information, including breast health and screening behaviors you can follow. You will also help to increase scientific knowledge about the effect of receiving breast cancer risk information and some possible ways to help understand and cope with that information. This knowledge can help guide health care professionals about how to provide such information and counseling.

### **Alternative Treatments**

The alternative to this study is to not participate and to receive this information from other resources in the community (for example, health care providers, printed information, or health-related organizations). Alternative treatment offered to women who want information about their risk of breast cancer includes primarily a discussion of known breast cancer risk factors and screening guidelines.

### **Costs**

There are no costs involved in participating in this study other than your time and travel costs. You will not be paid for being in the study or for any wages lost from taking part in the study. However, your parking expenses while attending study sessions will be covered by the study.

I have read and understand this page of the consent form:

\_\_\_\_\_  
Participant Initials/Date

\_\_\_\_\_  
Witness Initials/Date

**Confidentiality**

All of your study records will be kept strictly confidential as provided by law. Your personal identity will not be revealed in any publication or release of results. Representatives from the U.S. Army Medical Research, Development, Acquisition and Logistics Command are eligible to inspect the records of this research as a part of their responsibilities to protect human subjects in research. Study staff will have access to your personal data for the purposes of maintaining and updating your study records. These study records will be kept indefinitely for analysis and follow-up.

**Right to Withdraw**

Your decision to participate in the study is completely voluntary. You may drop out at any time, for any reason, without notice or consequence to you. However, we hope that you will come to all of the sessions and complete all of the forms, because the validity of the study depends on all women participating to the end of the study. Your regular health care will not be affected by your participation in this study.

**Voluntary Consent**

If you have any questions about the study or your rights as a volunteer, a study staff member will be on hand to answer them before you sign this consent form. Also, if you have any questions about your rights as a participant in this study, please call Karen Hansen at the Institutional Review Office of the Fred Hutchinson Cancer Research Center at 667-4941. If you have any questions at any time, you may call the BCA Nurse Counselor at 667-4095 or Dr. Barbara Cochrane, the principal investigator, at 667-6814.

\_\_\_\_\_  
Signature of Principal Investigator or Designee

\_\_\_\_\_  
Date

I have read the study description above and have initialed and dated each page of this form to indicate that the pages have been read and understood. I voluntarily consent to take part in this study. I have had an opportunity to ask questions and they have been answered to my satisfaction. I understand that I may drop out of the study at any time. I understand that I may ask further questions at any time and that I will receive a copy of this signed consent form for my records.

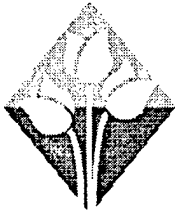
\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

## Risk Appraisal Information Sheet



## Breast Cancer Awareness Program

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### Breast Cancer Risk Information (MODEL)

**Date:**

**Participant's Name:**

This sheet describes information about your risk for breast cancer. The information comes from a computer analysis of your risk factors based on current scientific research on risk factors for breast cancer. **It is important to remember that this is an estimate of your risk based on population research studies.**

Based on the computer analysis of your risk factors, your risk of breast cancer is estimated to be:

\_\_\_\_\_ percent by age <<next 10 years>>

\_\_\_\_\_ percent by age <<80>>

Breast cancer risk appraisal scientists also describe this as a risk level of \_\_\_\_ based on "1" being a high risk and "4" being a low risk.

Your Breast Cancer Awareness (BCA) Nurse Counselor, <<Nurse Counselor's name>> will review this information with you during this risk information session. Please feel free to discuss any questions or concerns you may have with her.

Your Nurse Counselor will be discussing breast cancer risk and other aspects of breast cancer awareness during the group intervention sessions to be scheduled. While you are a participant in the study, please feel free to call your Nurse Counselor at 667-4095 if you have additional questions. You may also contact the BCA Principal Investigator, Dr. Barbara Cochrane at 667-6814.

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BCA Nurse Counselor

## Group Session Checklists



## Checklist for Group #1

### ☐ Cart with:

- |            |               |
|------------|---------------|
| 1. Tea     | 4. Mugs       |
| 2. Coffee  | 5. Condiments |
| 3. Cookies | 6. Napkins    |

### ☐ Parking stickers

### ☐ Participant notebooks with session #1 handouts and paper for writing notes

### ☐ Labels for name tags

### ☐ Visual Aids

1. Normal vs. abnormal cells
2. How cells metastasize
3. Breast cancer in perspective
4. Risk factors

### ☐ Risk booklets

### ☐ Index cards (5 for each participant) for life qualities activity

### ☐ Feedback forms with envelope

### ☐ Debriefing form

### ☐ Send attendance form to Elise

## Checklist for Group #2

☐ Cart with:

- |            |               |
|------------|---------------|
| 1. Tea     | 4. Mugs       |
| 2. Coffee  | 5. Condiments |
| 3. Cookies | 6. Napkins    |

☐ Parking stickers

☐ Stress management brochures

☐ Exercise booklets-“I walk-because” “Ten tips”

☐ Participant handouts for session #2

☐ Feedback forms with envelope

☐ Debriefing form

☐ Send attendance form to Elise

### Group #3 - Checklist

☐ Cart with:

- |            |               |
|------------|---------------|
| 1. Tea     | 4. Mugs       |
| 2. Coffee  | 5. Condiments |
| 3. Cookies | 6. Napkins    |

☐ Parking stickers

☐ Breast Model Suitcase and Small Breast Models

☐ Visual Aids

1. Breast Cancer Screening Program
2. Detection Methods
3. Anatomy of the Breast
4. Location of Breast Cancer
5. Possible Early Signs

☐ Participant Handouts for Session # 3

☐ Mammography bookmark

☐ AARP mammography booklet

☐ Fortune Cookies in a basket

☐ Cards with scenarios for helping friends

☐ Self-Breast Exam Video

☐ Feedback forms with envelope

☐ Debriefing form

☐ Parking Stickers if necessary

#### Checklist for Group #4

☐ Cart with:

- |            |               |
|------------|---------------|
| 1. Tea     | 4. Mugs       |
| 2. Coffee  | 5. Condiments |
| 3. Cookies | 6. Napkins    |

☐ Parking stickers

☐ Visual Aids

1. SOS

☐ Vase with flowers

☐ Participant handouts for session #4

☐ Feedback forms with envelope

☐ Debriefing form

☐ Send attendance form to Elise

## Timeline

BCA Timetable for SRSS Requirements and Responsibilities Project 311

| Tentative Dates for First Groups | Item | Activity                                   | What SRSS needs before this date   | What SRSS will do/provide   |
|----------------------------------|------|--|--|---|
| 5/8/96                           |      | Mailing to WHI sample                      | Sample--in electronic or scannable form<br>Recruitment brochure and postcard<br>Cover Letter<br>Mailing envelopes with postage imprint   | Print Labels<br>Assemble recruitment packets and mail<br>Personalize cover letter   |
| 5/8/96                           | A    | Receipt of Call                            | Access information for voice mail number   | Record VM messages.<br>Tracking: Login respondents, produce SCR's (Simplified Call Records).  |
| 5/15/96                          | B    | Screening/Scheduling                       | Screening script<br>Answers to questions participants may ask<br>Details about screening questions<br>Ind. Session slots for scheduling (from GZ)  | Interviewers will begin calling respondents<br>*Projected questions participants may ask<br>*Projected screening difficulties<br>Ci3 screens to screen and record addresses and individual appointments<br>Schedule participants, notify GZ |
| 5/22/96                          | C    | Packet 1 Mailed                            | Cover letter<br>Map and parking information for days/eves<br>9x12 envelopes with postage imprint<br>Questionnaire Booklet 1 returned at individual meeting and reviewed by nurse counselor | Print labels<br>Assemble and mail packet<br>Tracking: Label printing, 'ticking' daily reports for reminders about packet assembly, etc., weekly status reports, i.e., fully functional tracking system.                                     |
| 6/3/96                           | D    | Reminder call                              | Approval of Ind Session reminder call script   | *Draft of Ind. Session reminder call script<br>Interviewers will call and remind of appt.   |
| 6/5/-6/19/96                     | E    | Individual Sessions                        | Packet 2 materials to Ns Counselor:<br>Cover letter, questionnaire booklet 2, 9x12 stamped return envelopes  | Assemble packets  |
|                                  | F    | Receipt of packets 1 - completed materials |  | Packets will be logged in daily, edited for data entry & keyed in later using Rode-pc   |

BCA Timetable for SRSS Requirements and Responsibilities Project 311

| Tentative Dates for First Groups | Item | Activity              | What SRSS needs before this date   | What SRSS will do/provide   |
|----------------------------------|------|-----------------------|--|---|
| 6/12/96                          | G    | Reminders/thank yous  | Reminder/Thank you postcard<br>Stamps  | Print labels<br>Mail postcards  |
| 6/19/96                          | H    | Telephone reminders   | Packet 2 reminder script approval  | *Draft of packet 2 reminder script  |
| 6/12/96                          | I, J | Receipt of packet 2   | Need return envelopes to be addressed to SRSS  | Packets will be logged in daily, edited for data entry & keyed in promptly - 2nd pkt will receive edit callbacks for missing vital information so ppt can be randomized<br>Randomize participants and schedule for group sessions (intervention or control) |
| 6/31/96                          | K    | Grp session reminder  |  | Ns counselor will call and remind   |
| 7/2/ (9,16,23)                   | L    | Immed. group sessions |  |   |
| 8/15/96                          | M    | Packet 3 mailed       | Cover letter for packet 3<br>Questionnaire booklet 3<br>9x12 mailing envelopes with postage imprint<br>9x12 stamped return envelopes | Print labels<br>Assemble and mail packets   |
| 8/25/96                          | N    | Reminder/Thank yous   | Reminder/Thank you postcards for pkt 3<br>stamps   | Print labels<br>Mail postcards  |
| 8/29/96                          | O    | Telephone Reminders   |  | Interviewers will call & remind to send   |
| 8/22/96                          | P    | Receipt of packet 3   |  | Packets will be logged in daily, edited for data entry & keyed in later - 3rd pkt will receive edit callbacks for missing vital information   |
| Tentative Dates for First Groups | Item | Activity              | What SRSS needs before this date   | What SRSS will do/provide   |

Created 11/30/95

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Revised 4/29/96

BCA Timetable for SRSS Requirements and Responsibilities Project 311

|                    |     |                        |   |  |
|--------------------|-----|------------------------|---|--|
| 8/10/96;           | new | Tel remind re grp ses. |   | Ns counselor will call and remind  |
| 8/12 (19, 26, 9/2) | Q   | Delayed group sessions |   |  |
| 5/12/98            | R   | Packet 4 mailed        | Cover letter<br>Questionnaire booklet 4<br>9x12 mailing envelopes with postage imprint<br>9x12 stamped return envelopes | Print labels<br>Assemble and mail packets  |
| 5/12/98            | S   | Reminder/Thank you     | Reminder/Thank you postcard for pkt 4<br>stamps   | Print labels<br>Mail postcards   |
| 5/19/98            | T   | Telephone reminder     |   | Interviewers will call and remind to send  |
| 5/12/98 and on     | U   | Receipt of packet 4    | Possible remain (?)<br><br>Thank you letter to participants<br>stamps (& envelopes?)                                    | Packets will be logged in daily, edited for data entry & keyed in later - 4th pkt will receive edit callbacks for missing vital information<br>Print labels<br>Mail thank yous |



## Tracking Information

## **Breast Cancer Awareness: Tracking System**

The tracking system has been programmed to serve the following functions:

- Adds newly recruited participants from contact log
- Tracks receipt of questionnaires
- Tracks appointments for individual and group session
- Cues mailing of packets, reminder calls according to appointment dates with daily list printout
- Runs labels for those needing mailings
- Performs mail merge for personalized letters

## **Participant Certificate of Completion**

# Certificate of Recognition

Awarded to  
**Type in BCA Participant Name**

*For completing the Breast Cancer Awareness: Learning About Your Risk Group Sessions!*

Presented by  
**Breast Cancer Awareness Program**

Type in date of award

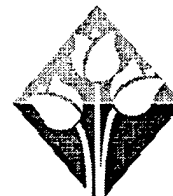
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Gretchen Zunkel, MN, ARNP  
Nurse Counselor

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Barbara Cochrane, RN, PhD  
Principal Investigator

## **Group Session Participant Evaluations**



## Breast Cancer Awareness Program

### Group Session #1 Feedback Form

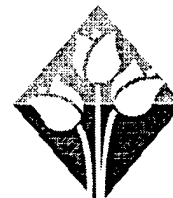
We would like feedback on the Breast Cancer Awareness Program session that just ended. Please fill in the blanks below with the appropriate number (1 through 5). Additional comments would be appreciated. The information you provide will be kept anonymous.

| Strongly Disagree<br>1 | Disagree<br>2 | Neutral<br>3 | Agree<br>4 | Strongly Agree<br>5 |
|------------------------|---------------|--------------|------------|---------------------|
|------------------------|---------------|--------------|------------|---------------------|

- \_\_\_\_\_ 1. I had no problems getting to the group session.  
*Comments:*
- \_\_\_\_\_ 2. The group session was held at a convenient time.  
*Comments:*
- \_\_\_\_\_ 3. The room was comfortable.  
*Comments:*
- \_\_\_\_\_ 4. The group size is appropriate.  
*Comments (too large/too small?):*
- \_\_\_\_\_ 5. The length of the group session was appropriate.  
*Comments (too long/too short?):*
- \_\_\_\_\_ 6. The content of the session was interesting.  
*Comments:*
- \_\_\_\_\_ 7. I learned some new information in this session.  
*Comments:*
- \_\_\_\_\_ 8. I enjoyed hearing from other members of the group.  
*Comments:*
- \_\_\_\_\_ 9. The Nurse Counselor who led the group was very knowledgeable.  
*Comments:*
- \_\_\_\_\_ 10. The Nurse Counselor who led the group was very supportive.  
*Comments:*
- \_\_\_\_\_ 11. I am looking forward to the next group session.  
*Comments:*

***Other comments?***

Thank you for taking the time to complete this form!



## Breast Cancer Awareness Program

### Group Session #2 and #3 Feedback Form

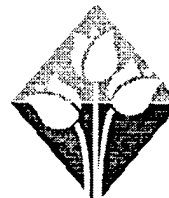
We would like feedback on the Breast Cancer Awareness Program session that just ended. Please fill in the blanks below with the appropriate number (1 through 5). Additional comments would be appreciated. The information you provide will be kept anonymous.

|                   |          |         |       |                |
|-------------------|----------|---------|-------|----------------|
| Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 1                 | 2        | 3       | 4     | 5              |

- \_\_\_\_\_ 1. The length of the group session was appropriate.  
*Comments (too long/too short?):*
- \_\_\_\_\_ 2. The content of the session was interesting.  
*Comments:*
- \_\_\_\_\_ 3. I learned some new information in this session.  
*Comments:*
- \_\_\_\_\_ 4. I enjoyed hearing from other members of the group.  
*Comments:*
- \_\_\_\_\_ 5. The Nurse Counselor who led the group was very knowledgeable.  
*Comments:*
- \_\_\_\_\_ 6. The Nurse Counselor who led the group was very supportive.  
*Comments:*
- \_\_\_\_\_ 7. I am looking forward to the next group session.  
*Comments:*

***Other comments?***

Thank you for taking the time to complete this form!



## Breast Cancer Awareness Program

### Group Session #4 Feedback Form

We would like feedback on the Breast Cancer Awareness Program session that just ended. Please fill in the blanks below with the appropriate number (1 through 5). Additional comments would be appreciated. The information you provide will be kept anonymous.

|                        |               |              |            |                     |
|------------------------|---------------|--------------|------------|---------------------|
| Strongly Disagree<br>1 | Disagree<br>2 | Neutral<br>3 | Agree<br>4 | Strongly Agree<br>5 |
|------------------------|---------------|--------------|------------|---------------------|

- \_\_\_\_\_ 1. The length of the group session was appropriate.  
*Comments (too long/too short?):*
- \_\_\_\_\_ 2. The content of the session was interesting.  
*Comments:*
- \_\_\_\_\_ 3. I learned some new information in this session.  
*Comments:*
- \_\_\_\_\_ 4. I enjoyed hearing from other members of the group.  
*Comments:*
- \_\_\_\_\_ 5. I would like to meet again with members of the group in the future.  
*Comments:*
- \_\_\_\_\_ 6. The Nurse Counselor who led the group was very knowledgeable.  
*Comments:*
- \_\_\_\_\_ 7. The Nurse Counselor who led the group was very supportive.  
*Comments:*
- \_\_\_\_\_ 8. These group sessions have been very valuable to me.  
*Comments:*

***Other comments?***

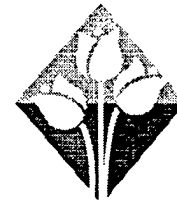
Thank you for taking the time to complete this form!



## **Group Session Facilitator Debriefing Form**



FRED  
HUTCHINSON  
CANCER  
RESEARCH  
CENTER



## Breast Cancer Awareness Program

### Group Session Debriefing Form

Date/Time \_\_\_\_\_

Location \_\_\_\_\_

Facilitator \_\_\_\_\_

Gp#/Session# \_\_\_\_\_

#### Scheduled Group Members:

Attended?(√) Name

\_\_\_\_\_ 1. \_\_\_\_\_

\_\_\_\_\_ 2. \_\_\_\_\_

\_\_\_\_\_ 3. \_\_\_\_\_

\_\_\_\_\_ 4. \_\_\_\_\_

\_\_\_\_\_ 5. \_\_\_\_\_

\_\_\_\_\_ 6. \_\_\_\_\_

\_\_\_\_\_ 7. \_\_\_\_\_

\_\_\_\_\_ 8. \_\_\_\_\_

\_\_\_\_\_ 9. \_\_\_\_\_

\_\_\_\_\_ 10. \_\_\_\_\_

\_\_\_\_\_ 11. \_\_\_\_\_

\_\_\_\_\_ 12. \_\_\_\_\_

Session started \_\_\_\_\_

Session ended \_\_\_\_\_

Total length of session \_\_\_\_\_

**Session Debrief**

Overall sense of how the session went and your role:

Logistical issues (setting, timing, interruptions, etc.):

Group dynamics:

Participants' reactions to and discussion about content:

Your sense of participants' understanding of content:

Unusual/interesting questions/comments:

Strategies that worked particularly well and why you think they worked:

Strategies or approaches that could be improved/didn't work well (and why):

Other comments: